University of Alberta

Outcomes Following an Implementation Program of a Mechanical Ventilation Weaning Protocol for Critically Ill Adults

by

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A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Nursing

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"I want the protocol to give us autonomy, to be proactive and assertive so our profession can make changes" (GSICU Registered Nurse, 2004).

Dedication

Outcomes Following an Implementation Program of a Mechanical Ventilation Weaning Protocol for Critically Ill Adults is dedicated to my partner,

Major (Retired) Barry John McLean, CD1.

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CHAPTER ONE

Introduction

Mechanical ventilation, broadly defined, is a method for providing adequate gas exchange in many disease states. The indications for initiating mechanical ventilation are traditionally based on specific values of arterial oxygenation and clinical judgment (Pierson, 2002). Mechanical ventilation is an intervention required in over 90% of critically ill adults in intensive care units (Meade, Guyatt, Griffith et al., 2001). Critically ill patients spend approximately 41% of their time receiving mechanical ventilation (Esteban, Alía, Ibañex et al., 1994), and this time may be higher for patients with comorbid chronic disease states. Prolonged mechanical ventilation, defined as mechanical ventilation beyond three days (Burns, 1999), can increase health care costs due to longer intensive care unit stays, costs associated with mechanical ventilation, and exposure of patients to unnecessary risks. These risks include: increased mortality, ventilator associated pneumonia, airway trauma, and increased sedation needs (Cook et al., 1998; Marelich et al., 2000; Slutsky & Tremblay, 1998) and decreased staff, patient, and family satisfaction (Burns, 1999). On the other hand, premature discontinuation of mechanical ventilation can contribute to failed extubation requiring reintubation (MacIntyre et al., 2001). Rates of reintubation range from 4 to 33% (Epstein & Ciubotaru, 1997; Vallverdú et al., 1998). Reintubation potentially induces harm with associated airway trauma, gastric aspiration, acute lung injury, cardiovascular compromise, and hypoxia (Esteban, Alía, Ibañex et al., 1994). Reintubation carries an estimated eight times higher risk of nosocomial pneumonia and a six to twelve times increased mortality (Ely et al., 2001). Thus, discontinuation of mechanical ventilation

must be balanced against the possibility of premature extubation and unnecessary prolonged ventilatory support.

The process of weaning critically ill adults from mechanical ventilation refers to the phenomenon of gradual discontinuation of mechanical ventilation (Ely et al., 2001). While a variety of approaches are available to wean patients from mechanical ventilation, there is evidence from well-designed, well-conducted controlled clinical trials that suggests protocol directed weaning consistently reduces time spent on mechanical ventilation (Ely et al., 1996; Kollef et al., 1997; Marelich et al., 2000), reduces ventilator associated complications (MacIntyre et al., 2001), and reduces the rate of reintubation (Ely et al., 1996). Although, there is evidence suggesting that protocol directed weaning improves outcomes (Ely et al., 1996; Keller et al., 1997; Marelich et al., 2000), there are no data to support endorsing any one specific protocol. Studies to date have compared computer or physician-directed weaning to protocol directed weaning led by respiratory therapists and nurses (Ely et al., 1996; Kollef et al., 1997; Marelich et al., 2000; Strickland & Hasson, 1993).

Protocols have the potential to create resentment and frustration among health care professionals because procedural care may be perceived as removing clinical judgment without considering all facets of the patient (Morris, 2003). Thus, inherent with any change directed at improving patient safety and outcomes calls upon gaining an understanding of the clinical staff's perceptions about a current procedure. An improvement in staff's perceptions related to a proposed change in a procedural protocol has been associated with decreases in errors, patient length of stay, and employee attrition (Sexton, Helmreich, Pronovost, &Thomas, 2003). Considerable research has been

dedicated to the importance of the most effective and safest method of weaning patients from mechanical ventilation, yet research describing the implementation process and compliance of protocol directed weaning is minimal (Ely, Bennett et al., 1999; Saura et al., 1996).

The Model for Accelerating Improvement (Langley, Nolan, Nolan, Norman & Provost, 1996 as cited in Rainey, Kabcenell, Berwick & Roessner, 1998), which was initially developed as a framework for accelerating improvement in clinical outcomes, is a process which guides health care teams in making procedural changes. The Model for Accelerating Improvement has two parts (Appendix A). The first part is to define the endpoint of the initiative by focusing on three simple questions: (1) what are we trying to accomplish? (2) how will we know a change is an improvement? and, (3) what changes can we make that will result in improvement? The second part is the Plan-Do-Study-Act (PDSA) cycle to test and implement procedural changes in work settings. The PDSA cycles test small changes and builds sequentially on the knowledge of each cycle. The first step, 'Plan', of each cycle involves stating the objective of the cycle, making predictions about what will happen, and developing a plan to test the change using evidence based medicine. The second step, 'Do', of each cycle involves carrying out the test, documenting problems and unexpected observations, and a beginning analysis of the data. The third step, 'Study', of each cycle involves completing the analysis of the data, comparing the data to predictions, and summarizing what was learned. The fourth step, 'Act', of each cycle involves determining what modifications should be made, and preparing a plan for the next cycle. The completion of each PDSA cycle builds for the start of the next cycle (Rainey et al., 1998).

The Phoebe Putney Memorial Hospital in Georgia used The Model for Accelerating Improvement to reduce length of stay by 25% for patients requiring mechanical ventilation, by reducing the median time on mechanical ventilation from 5.5 days to 3 days, while maintaining or improving outcomes, and reducing costs (Kollef, Horst, Prang, & Brock, 1998; Rainey et al., 1998). The General Systems Intensive Care Unit (GSICU) at the University of Alberta Hospital implemented an evidence-based mechanical ventilation weaning protocol in December 2002 (Appendix B); however the compliance in utilizing the protocol was estimated at less than 1%. The effectors and resistors for protocol abatement and compliance, and the outcomes of protocol directed weaning in the GSICU were undetermined.

Purpose of the Study

The purpose of this study was to assess the outcomes before and after an implementation program for a mechanical ventilation weaning protocol with a heterogeneous adult critical care population in the GSICU at the University of Alberta Hospital.

The research hypotheses tested were:

1. There will be a decrease in failed extubations in the critically ill adult following an implementation program of a mechanical ventilation weaning protocol as compared to those whose weaning is protocol directed before the implementation program.
2. There will be a decrease in rate of ventilator associated pneumonia in the critically ill adult following an implementation program of a mechanical

ventilation weaning protocol as compared to those whose weaning is protocol directed before the implementation program.

3. There will be a decrease in length of time on mechanical ventilation in the critically ill adult following an implementation program of a mechanical ventilation weaning protocol as compared to those whose weaning is protocol directed before the implementation program.
4. There will be an increase in the multidisciplinary staff's understanding of the mechanical ventilation weaning protocol following an implementation program as compared to understanding of the mechanical ventilation weaning protocol before the implementation program.
5. There will be an improvement in the multidisciplinary staff's perceptions of the safety climate following an implementation program of a mechanical ventilation weaning protocol as compared to the perceptions of the safety climate before the implementation program.
6. There will be an increased compliance rate of utilizing the mechanical ventilation weaning protocol following an implementation program as compared to before the implementation program.

The relationships among rate of failed extubations, rate of ventilator associated pneumonia, and length of time on mechanical ventilation, and Acute Physiology and Chronic Health Evaluation (APACHE) II score, age, gender, reason for intubation, Riker Sedation Agitation Scale (SAS), head of bed elevation, placement of feeding tube, and subglottic secretion drainage using EVAC ™ tubes, were also examined. Finally, the effectors and resistors to protocol directed weaning were identified.

Significance of the Study

Adult critical care is a specialty that is facing challenges associated with the aging baby boomers, advancements in technology, increasing pharmaceutical interventions, role expansion of health care professionals, and life supporting strategies. At the same time, clinicians are faced with challenges and responsibilities of narrowing the gap between current practice and evidence-based practice while maximizing patient safety and care. Protocol directed weaning has been suggested to be an effective and safe strategy in the management of mechanical ventilation, yet there is a paucity of literature about "how to" utilize and transfer this knowledge to the practice setting. Protocol directed weaning has been implemented in the GSICU since December 2002, yet the extent of staff knowledge of this practice was unknown.

Historically, transfer of research to the practice setting has varied across disciplines. The development in educational preparation for various disciplines has called upon research to find ways of integrating research with current practice, with an end goal being evidence-based practice for all disciplines. By engaging the multidisciplinary team in the process of making procedural changes, such as The Model for Accelerating Improvement, staff and key stakeholders may be more likely to utilize the knowledge described in the literature. At the same time, clinicians will be meeting the challenges and assuming responsibility collectively, in narrowing the gap between current practice and evidence-based based practice.

CHAPTER TWO

Literature Review

Cochrane Data Base of Systematic Reviews, MEDLINE, EMBASE, DARE, and CINAHL from 1990 to 2004 were reviewed, and a hand search of identified article reference lists was conducted. Literature prior to 1990 was not searched because the heightened interest of weaning patients from mechanical ventilation began in the mid-nineties, and the first randomized controlled trial was published in 1994 (Brochard et al., 1994). Ninety-three relevant English articles were reviewed and sorted into four categories: (1) studies addressing the process of weaning; (2) studies addressing predictors of successful weaning; (3) studies addressing approaches of weaning; and (4) studies addressing protocol directed weaning.

Process of Weaning

The starting point for weaning is extensively described, and ranges from the onset of mechanical ventilation to the recovery of the underlying respiratory failure. Meade, Guyatt, Griffith, et al. (2001) proposed, "One reasonable conceptualization is weaning beginning with the onset of mechanical ventilation" (p. 398S). Ely, Baker, Evans, and Haponik (1999) do not explicitly define weaning, however suggest, "Mechanical ventilation should be discontinued as soon as respiratory failure has resolved and patients are able to breathe spontaneously…" (p. 582). Similarly, weaning was described as the recognition of adequate recovery from acute respiratory failure (MacIntyre et al., 2001). This description is consistent with another in that "…the weaning process should proceed as soon as the patient is ready…" (Strickland & Hasson, 1993, p. 1220).

In extrapolating these various conceptualizations and combining them with current practice, it seems most logical that weaning proceeds in stages, with the starting point being intubation and the recognition for readiness to reduce mechanical ventilation support, to the end stage being a successful extubation. The first stage involves a formal assessment for the potential of success in reducing mechanical ventilation, or more specifically, an assessment of patients' readiness to tolerate reductions in mechanical ventilation support. As part of this formal assessment, medical therapy must be optimized. This should not be confused with reversal of the underlying cause, as there are circumstances in which it is not realistic and curative organ therapy is not a goal. The second stage involves a step-wise approach in reducing mechanical ventilation leading to the third stage of discontinuation of mechanical ventilation and extubation.

Predictors of Successful Weaning

Various criteria have been tested to predict success in weaning patients from mechanical ventilation. Predictors for each stage of weaning are identified. Specifically, predictors which differentiate between those patients who are able to breathe spontaneously and those who are unable, and predictors which differentiate between successful and failed extubations. Studies designed to predict weaning success have been conducted with heterogeneous critically ill populations, or have focused on specific populations such as those with neurologic disease, pulmonary disease, or heart failure.

Meade, Guyatt, Cook, et al. (2001) conducted a review of 65 observational studies of predictors of successful weaning and identified from these studies 462 predictors. The best predictors of unassisted breathing included: respiratory rate <38 breaths/minute; rapid shallow breathing index <100 breaths/minute/liter; a product of rapid shallow

breathing index and occlusion pressure < 450 cm H_2O breaths/min/liter; and a knowledge-based system for adjusting pressure support. The predictors of successful extubation included: minute volume, respiratory rate, tidal volume, rapid shallow breathing index, rapid shallow breathing index standardized to body weight, maximal inspiratory pressure, and CROP (compliance, rate, oxygenation, pressure). Of note, the rapid shallow breathing index was the strongest predictor of extubation success. However, Meade, Guyatt, Cook, et al. (2001) concluded that none of the predictors are extremely powerful and yield inconsistent results. Despite this, advantages to using these indices include: predicting weaning readiness in trials of unassisted breathing and of successful extubation, all indices can be obtained at the bedside, and all only need simple non-invasive calculation.

Approaches to Weaning

Controversy exists on how weaning should best be performed. Various approaches to weaning critically ill adults from mechanical ventilation have become the accepted standard or usual practice of care. Official recognition of various approaches to weaning surfaced in 1994 when the first randomized controlled trial compared three modes of weaning from mechanical ventilation (Brochard et al., 1994). Today, ventilator modes used in weaning include spontaneous breathing trials, pressure support ventilation (PSV), synchronized intermittent mandatory ventilation, and non-invasive positive-pressure ventilation (Hess, 2001). Meade, Guyatt, Sinuff, et al. (2001) reviewed 16 randomized controlled trials comparing weaning modes and concluded that PSV or multiple daily T-piece trials were superior to intermittent mandatory ventilation.

Other factors identified that influence the weaning process include: the physiological effects of high fat and low carbohydrate on CO_2 production and respiratory quotient; the use of non-invasive positive pressure ventilation in the post-extubation phase; the use of oximetry and capnography; the administration of recombinant growth hormone; the use of relaxation biofeedback; and the use of acupuncture in averting largyngospasm (Cook et al., 2001). These may offer effective methods of weaning patients from mechanical ventilation; however, all studies reviewed were underpowered for clinically significant outcomes (Cook et al., 2001).

Protocol Directed Weaning

Protocol directed weaning, a tool in the management of mechanical ventilation, utilizes the skills and expertise of the multidisciplinary team. Protocol directed care " …can reduce unnecessary variation in clinical practice and have produced favorable changes in patient outcomes" (Morris, 2003). Four randomized controlled trials and 14 nonrandomized trials comparing protocol directed weaning to standard weaning in critically ill adults were identified in the literature. One of the four randomized controlled trials compared computer-directed weaning to physician weaning (Strickland & Hasson, 1993). The other three randomized controlled trials compared protocol directed weaning, lead by respiratory therapists and nurses, to physician-directed weaning (Ely et al., 1996; Kollef et al., 1997; Marelich et al., 2000).

Strickland and Hasson (1993) compared computer-directed weaning to physician directed weaning. The average time receiving mechanical ventilation prior to weaning for the computer-directed weaning group (n=9) was 13.4 ± 7.8 days and 14.5 ± 11.1 days for the physician directed weaning group (n=6). Ely et al. (1996) compared two groups of

subjects who randomly received either "usual care" (n=151) and protocol directed weaning (n=149). Usual care was not defined but had daily screening of various hemodynamic respiratory indicators, with no other intervention (Ely et al., 1996). The protocol directed weaning group received daily screening followed by a trial of spontaneous breathing that was deemed successful if the subject could breathe for two consecutive hours without mechanical ventilation. The time spent receiving mechanical ventilation was 4.5 days for the protocol directed group versus 6 days for the usual care directed group (p=0.003). The weaning time, defined as the number of days from the time the patient had a successful screening test to the discontinuation of mechanical ventilation, was 1 day for the protocol directed group versus 3 days for the usual care directed group. The rates of reintubation within 48 hours of extubation were 3.3% for the protocol directed group versus 7.9% for the "usual care" directed group (p=0.08).

Kollef et al. (1997) also compared protocol directed weaning to physician directed weaning. The hypothesis was that nurses and respiratory therapists could safely and effectively wean patients from mechanical ventilation using guidelines. The duration for mechanical ventilation for the protocol directed group (n=179) was 69.4$\pm$123.7 hours and 102$\pm$169.1 hours for the physician directed group (n=178) (p=0.029); 12.8% of the subjects required reintubation in the protocol directed group, while 10.1% of the patients required reintubation in the physician directed group (p=0.417). Finally, Marelich et al. (2000) compared physician directed weaning to protocol weaning led by respiratory care practitioners and nurses and examined the efficacy of a single ventilator management protocol and the effect of the ventilator management protocol on incidence of ventilator associated pneumonia. They found that the duration of mechanical ventilation for the

physician directed group (n=169) was a median of 124 hours and 68 hours for the ventilator management protocol group (n=166) (p=0.0001). The incidence of ventilated associated pneumonia was 11.8% for the physician directed group and 6.6% for the ventilator management protocol group (p=0.100).

Thus, all randomized controlled studies reported a reduction in length of time on mechanical ventilation, reported as 'duration of weaning', 'duration of mechanical ventilation', and 'duration of intubation', for critically ill adults whose weaning was protocol directed compared to those whose weaning was physician or computer-directed (Ely et al., 1996; Kollef et al., 1997; Marelich et al., 2000; Strickland & Hasson, 1993). Two randomized controlled trials reported a decreased rate of reintubation for critically ill adults whose weaning was protocol directed (Ely et al., 1996; Strickland & Hasson, 1993 as cited in Ely et al., 2001), and one randomized controlled trial reported a decreased rate of ventilator associated pneumonia for critically ill adults whose weaning was protocol directed (Marelich et al., 2000).

All fourteen nonrandomized trials reported length of time on mechanical ventilation (Burns et al., 1998; Burns et al., 2003; Chan et al., 2001; Djunaedi et al., 1997; Dries, McGonigal, Malian, Bor, & Sullivan, 2004; Duane et al., 2002; Foster, Conway, Pamulkov et al., 1984; Grap et al., 2003; Horst, Mouro, Hall-Jenssens, & Pamukov, 1998; Kollef et al., 1998; Krishnan, Moore, Robeson, Rand, & Fessler, 2004; Rotello, Warren, Jastremski, & Milewski, 1992; Saura et al., 1996; Wood et al., 1995). Rate of failed extubations was reported in 7 of the 14 nonrandomized trials (Burns et al., 2003; Chan et al., 2001; Dries et al., 2004; Horst et al., 1998; Krishnan et al., 2004; Saura et al., 1996; Wood et al., 1995). Rate of ventilator associated pneumonia was reported in

two nonrandomized trials (Dries et al., 2004; Kollef et al., 1998). Three of the nonrandomized trials reported protocol compliance (Burns et al., 2003; Duane et al., 2002; Krishnan et al., 2004).

The first nonrandomized trial in the literature was published in 1984 when Foster et al. prospectively studied early extubation following coronary artery bypass grafting. This study compared respiratory therapist led protocol directed weaning (n=36) to standard weaning practices (n=27). The mean length of time receiving mechanical ventilation was 9.8±4.4 hours for the protocol directed group versus 16.5±8.0 hours for the standard weaning group ($p<0.01$). Rotello et al. (1992) compared nurse led protocol directed weaning using arterial blood gas analysis and pulse oximetry measurements to "unstandardized" physician directed weaning. Length of time receiving mechanical ventilation was not reported. The mean duration of weaning in the protocol group (n=50) was 170±93 minutes versus 307±131 minutes in the unstandardized physician directed group (n=13) ($p<0.0001$). Wood et al. (1995) compared protocol directed weaning led by respiratory therapists (n=209) to standard physician directed weaning (n=75) with a stable post coronary artery bypass surgical population. After four months of initiating the protocol, the eligibility criteria were expanded to include more unstable patients; i.e., those with an intra-aortic balloon pump, those who had undergone previous cardiac surgery, and those who had undergone cardiac valve surgery. A physician's order was required to initiate the protocol. This study reported that the respiratory therapist protocol group had a significantly shorter duration of mechanical ventilation with a median ventilation time of 16.8 hours as compared to 18.6 hours in the physician directed group ($p=0.02$). Failed extubation was not defined; however, one patient in the protocol

group required reintubation within 24 hours of extubation, and three patients in the physician directed group required reintubation.

Saura et al. (1996) compared protocol directed weaning to standard weaning. The hypothesis was that a weaning protocol could directly influence the management of patients receiving mechanical ventilation. The duration of mechanical ventilation for the protocol directed weaning group (n=51) was 10.4±11.6 days versus 14.4±10.3 days for the standard weaning group (n=50) ($p<0.05$). There was a non-statistically significant reintubation rate of 17% for the protocol directed weaning group versus 14% for the standard weaning group. The reasons for failure in extubation were reported as cough, nosocomial pneumonia, bronchospasm, atelectasis, sepsis, and subsequent emergency surgical procedure.

Djunaedi et al. (1997) compared respiratory therapist led protocol directed weaning (n= 57) and standard physician directed weaning (n=50). A physician's order was not required to initiate the protocol, however a physician's order was required to adjust the ventilator settings. This study reported a median duration of mechanical ventilation as 3.89 days in the respiratory therapist led protocol directed weaning group versus 3.18 days in the physician directed weaning group ($p=0.39$).

Burns et al. (1998) compared nurse and respiratory therapy led protocol directed weaning to physician directed weaning. In this study, the protocol directed weaning required a physician's order to initiate. This study reported no statistically significant difference in mean length of time receiving mechanical ventilation: 11.6 days in the protocol group (n=74) versus 12.9 days in the physician directed group (n=101). Horst et al. (1998) compared protocol directed weaning led by respiratory therapists to surgeon

directed weaning with a surgical intensive care unit which included liver and pancreas transplants. Permission for the respiratory therapists to utilize the protocol was given by the patient's surgeon. The length of time receiving mechanical ventilation in the protocol group (n=515) was 112.6±164.0 hours versus 170.6±164.0 hours in the surgeon directed weaning group (n=378) ($p<0.01$). Failed extubation was not defined. Reintubation was reported as "accidental" extubation occurring within 24 hours of extubation that required reintubation. This study reported no difference in reintubation rates. "Accidental" extubation requiring reintubation was reported in 0.38% of the protocol group and 1.6% of the surgeon directed group.

Kollef et al. (1998) summarized studies which compared protocol directed weaning led by nurses and respiratory therapists to physician directed weaning in three intensive care units. They reported that in one surgical intensive care unit, a significant reduction in length of time receiving mechanical ventilation in the nurse and respiratory therapist led protocol directed group (n=347) with a mean duration of mechanical ventilation of 121.90 hours compared to the physician directed weaning group (n=378) with a mean duration of mechanical ventilation of 170.60 hours. In the second medical/surgical intensive care unit, there was a median duration of mechanical ventilation of 3 days in the respiratory therapist led protocol directed group (n=53) compared to 6 days in the physician directed weaning group (n=35). In the third medical/surgical intensive care unit, the study reported an average duration of mechanical ventilation of 2.9 days in the nurse and respiratory therapist led protocol directed group compared to 4.7 days in the physician directed weaning group. The rate of ventilator

associated pneumonia ranged from 10 to 20% in the physician directed weaning group compared to 1 to 11% in the nurse and respiratory therapist led protocol directed group.

Chan et al. (2001) compared multidisciplinary protocol directed weaning (n=47) to a Canadian database of 183 patients comprised of eight centres. In this study a physician's order was required to initiate the weaning protocol. There was no significant difference reported between the two groups with respect to duration of mechanical ventilation and rate of reintubation. The length of time receiving mechanical ventilation for the multidisciplinary protocol directed group was 6.7±6.5 days versus 6.2±7.0 days in the historical group. The rate of reintubation was 10.6% for the multidisciplinary protocol directed group versus 17.4% in the historical group.

Duane et al. (2002) compared respiratory therapist led protocol directed weaning and physician directed weaning from mechanical ventilation in a trauma intensive care unit. This study reported length of time receiving mechanical ventilation and protocol compliance. The length of time receiving mechanical ventilation was 6.1±9.1 days for the respiratory therapist led protocol directed group (n=160) versus 6.3±10.1 days for the physician directed group (p=0.83). The study performed a subgroup analysis and those patients who received long term mechanical ventilation, defined as "…ventilator length of stay greater than or equal to 3 SDs above the mean ventilator length of stay were excluded" (Duane et al., 2002). The subgroup analysis reported length of time receiving mechanical ventilation as 4.94±6.35 days for the respiratory therapist led protocol directed group (154) versus 4.93±6.96 days for the physician directed group (n=162) (p=0.98). Protocol compliance was monitored by the respiratory therapist supervisor who followed ventilator forms. The protocol compliance was reported as a percentage

per month and ranged from 50 to 100% during the first year of its use, with a decrease in compliance of 50% ten months following implementation.

Burns et al. (2003) compared protocol directed weaning led by the multidisciplinary team (n=595) to standard weaning from mechanical ventilation (n=510) in five intensive care units with patients who had received mechanical ventilation for greater than three days. A physician's order was required to follow the protocol. A reduction of median duration of mechanical ventilation of 9 days occurred in the postprotocol group versus 10 days in the preprotocol group of all units combined ($p<0.0001$). Unsuccessful extubation was defined as reintubation or reventilation within 24 hours of extubation. This study reported a rate of 14% unsuccessful extubations in the preprotocol group and an increase rate of 16.8% in the postprotocol group (n=86/510), with no significance difference. Protocol compliance was discussed in this study yet it was not explicitly defined. Protocol 'adherence' was monitored by advanced practice nurses and when they were not present to guide the use of the protocol, the protocols were not followed. Protocol compliance ranged from 10 to 30%, and reasons for low compliance were: physician unfamiliarity with the protocol; inconsistencies in seeking an order from the physicians; and lack of stationary assignments by the respiratory therapists applying the protocol.

Grap et al. (2003) compared outcomes before and after implementation of protocol directed weaning. Physician's approval was required to make a decision to extubate after following the protocol. Length of time receiving mechanical ventilation was a mean of 5.59 days after protocol implementation (n=459) versus 7.00 days before protocol implementation (n=459) ($p=0.02$).

Dries et al. (2004) compared protocol directed weaning led by nurses and respiratory therapists (n=336) and standard physician directed weaning (n=314) in a multidisciplinary surgical intensive care unit. A physician's order to routinely extubate a patient was not required. The length of time receiving mechanical ventilation was 3±4.7 days in the nurse and respiratory therapist led protocol directed weaning group versus 5±4.3 days in the standard physician directed weaning group ($p<0.001$). Failed extubation was defined as reintubation within 72 hours of extubation. The rate of reintubation was 7.4% in the nurse and respiratory therapist led protocol directed weaning group compared to 13.7% in the standard physician directed weaning group ($p=0.013$). The rate of ventilator associated pneumonia was 5% in the nurse and respiratory therapist led protocol directed weaning group compared to 15% in the standard physician directed weaning group ($p<0.001$).

Krishnan et al. (2004) compared nurse and respiratory therapist led protocol based weaning (n=154) and "usual" physician directed weaning (n=145) in a closed medical intensive care unit, and patients were assigned to either group based on their hospital number. The study does not report whether a physician's order was required to initiate the protocol or extubate the patient. The median length of time receiving mechanical ventilation was 60.4 hours in the nurse and respiratory therapist led protocol directed weaning group compared to 68 hours in the 'usual' physician directed weaning group ($p=0.61$). Patients were considered to have passed an extubation if they were able to breathe unassisted for 48 hours. The reintubation rate was 10.3% in the nurse and respiratory therapist led protocol directed weaning group versus 9% in the 'usual' physician directed weaning group, which was not significant. Protocol compliance was

determined by documentation review and was reported to be as high as 86.1%. Like other studies, protocol compliance was not explicitly defined.

Thus, 7 of the 14 nonrandomized trials reported a statistically significant reduction in length of time on mechanical ventilation for critically ill adults whose weaning was protocol directed compared to those whose weaning was physician directed (Burns et al., 2003; Dries et al., 2004; Foster et al., 1984; Grap et al., 2003; Horst et al., 1998; Saura et al., 1996; Wood et al., 1995). One study reported a statistically significant reduction in reintubation for critically ill adults whose weaning was protocol directed (Dries et al., 2004), and one study reported a statistically significant decreased incidence of ventilator associated pneumonia for critically ill adults whose weaning was protocol directed (Dries et al., 2004).

CHAPTER THREE

Method

The purpose of this study was to assess the outcomes before and after an implementation program for a mechanical ventilation weaning protocol with a heterogeneous adult critical care population in the GSICU at the University of Alberta Hospital.

Design

A prospective comparative design, before and after implementing The Model for Accelerating Improvement (Langley et al., 1996 as cited in Rainey et al., 1998) (Appendix A), was used to assess the effectiveness of a protocol directed weaning protocol. Pre-intervention data were obtained with the first 103 critically ill adults enrolled in the study. Data were collected from patient intubation to 48 hours post-extubation.

Once pre-intervention data were collected, the PDSA cycles of The Model for Accelerating Improvement (Langley et al., 1996 as cited in Rainey et al., 1998) were conducted. The first PDSA cycle assessed the clinical staff's perceptions through focus group sessions (Appendix C), safety climate survey (Appendix D), and a weaning protocol understanding survey (Appendix E). The change being tested with the first PDSA cycle was to assess the multidisciplinary staff's perceptions of the mechanical ventilation weaning protocol and safety climate. It was predicted that by assessing the staff's perceptions of the mechanical ventilation protocol, buy-in and comfort level in utilizing the protocol from essential stakeholders would be improved. It was also predicted that by engaging the clinical staff, staff's perceptions of the safety climate

would be improved. Once the PDSA cycle for assessing the staff's perceptions of the mechanical ventilation weaning protocol and culture of safety were conducted, the second PDSA cycle was conducted. The change being tested with this cycle was the increased awareness of how the mechanical ventilation weaning protocol contributes to decreasing the incidence of failed extubations, rate of ventilator associated pneumonia, and length of time on mechanical ventilation in critically ill adults. It was also predicted that an increased awareness would contribute to increase compliance in utilizing the protocol by essential stakeholders. This change in awareness was facilitated with learning sessions that were conducted with the multidisciplinary clinical team. Once the PDSA cycles were conducted, the post-intervention data with the next 100 critically ill adults were collected.

Sample

A consecutive sample of 203 patients (103 pre-intervention, 100 post-intervention) were enrolled from the GSICU at the University of Alberta Hospital over a five month period. The organizational structure of the GSICU is a closed unit in a university teaching hospital, servicing the most northern metropolitan city in North America and the rural north of Canada. The GSICU admits 90 to 100 patients a month and 90% of these patients are intubated. The GSICU has a heterogeneous population with admitting diagnoses of trauma, transplant, sepsis, cancer, overdose, multi-system organ failure, shock, and respiratory failure. The GSICU is currently funded for 29 beds, and staffing usually allows for the operation of 24+/- 2 beds. The University of Alberta Hospital has separate Cardiac and Neuroscience Intensive Care Units.

Inclusion criteria for the study were as follows: (a) 18 years of age and older; (b) receiving mechanical ventilation via endotracheal intubation; and (c) eligible to be on the GSICU mechanical ventilation weaning protocol. Exclusion criteria were as follows: (a) extubated within the last 48 hours; (b) laryngeal disease or trauma; (c) suspected or confirmed Severe Acute Respiratory Syndrome (SARS); (d) receiving unconventional forms of mechanical ventilation; i.e., home ventilation, high frequency jet ventilation or oscillation; (e) those patients with adult respiratory distress syndrome (ARDS); and (f) weaning from mechanical ventilation is not a goal; i.e., the philosophy of care is to withdraw or withhold organ support.

The multidisciplinary team involved in the implementation program for protocol directed weaning consisted of GSICU clinical staff. The GSICU employs 205 staff, including 123 (60%) Registered Nurses, 24 (11.7%) Respiratory Therapists, 16 (7.8%) Nursing Attendants, 11 (5.4%) Attending Intensivists, 8 (3.9%) Administrators, 7 (3.4%) Rotating Residents, 3 (1.5%) Clinical Nurse Educators, 2 (0.97%) Dieticians, 2 (0.97%) Research Coordinators, 2 (0.97%) Pharmacists, 2 (0.97%) Social Workers, 2 (0.97%) Nurse Practitioner Interns, 1 (0.48%) Aboriginal Cultural Helper, 1 (0.48%) Physical Therapists, and 1 (0.48%) Chaplain/Pastoral Care.

Definitions of Terms

Protocol Directed Weaning is the algorithm developed and utilized by the GSICU multidisciplinary team at the University of Alberta Hospital since December 2002, with the starting point being optimization of medical treatment and recognition for readiness to reduce mechanical ventilation support, to the end stage being aimed at successful mechanical ventilator discontinuation (Appendix F). Following preliminary content

analysis of the focus group sessions, the starting point of the algorithm was revised as being reversal of underlying cause and recognition for readiness to reduce mechanical ventilation support, to the end stage being aimed at successful mechanical ventilator discontinuation (Appendix B).

The Model for Accelerating Improvement was initially developed as a framework for accelerating improvement in clinical outcomes and is a process which guides teams in making rapid improvements (Langley et al., 1996). The Model has two parts. The first part is to define the endpoint of initiatives by focusing on three simple questions. The second part of the Model is the Plan-Do-Study-Act (PDSA) cycle to test and implement changes in work settings (Rainey et al., 1998) (Appendix A).

Safety Climate refers to a culture of safety that encourages data collection and reporting (Piotrowski, 2002), reducing blame, involving leadership (Wong, 2002), or focusing on systems (Krumberger, 2001). Theoretical components required in constructing a culture of safety are: commitment to safety is articulated at all levels of an organization; commitment to safety is articulated in providing necessary resources, incentives, and rewards; the primary priority is safety and this may mean production and efficiency may be secondary priorities; communication at and between all levels is frequent and candid; unsafe acts are rare despite high levels of production; errors and problems are transparent when they occur; organizational learning is a shared value; and behaviour at all levels focuses on problem solving to improve the system rather than on individual blame (Singer et al., 2003). The safety climate was assessed by the Safety Climate Survey (Appendix D). The questionnaire consists of 19 questions plus demographic information,

and uses a six point scale ranging from not applicable, agree strongly, agree slightly, neutral, disagree slightly to disagree strongly.

Protocol Directed Weaning Understanding is knowledge of the reduction of mechanical ventilatory support aimed at successful extubation without any adverse effects on the patient. Staff understanding was assessed by the Protocol Directed Weaning Survey. The Protocol Directed Weaning Survey is a survey designed to test the staff's understanding of evidence based protocol directed weaning, and consists of three questions with five possible points for each question for a total of 15 points (Appendix E).

Failed Extubation is reintubation within 48 hours of tracheal decannulation as a result of one or more of the following: inability to protect airway; need for broncopulmonary toilet; unable to clear secretions; PaO_2 <70% on 50% oxygen or <55% on room air; $PaCO_2$ > 55 mmHg; pH < 7.25; CO_2 narcosis; cardiac arrest; or respiratory arrest.

Successful Extubation is continuous independence from mechanical ventilation and tracheal or endotracheal tube for more than 48 hours after extubation (Esteban, Alía, Gordo et al., 1997)

Ventilator Associated Pneumonia is the occurrence of progressive or new radiographic pulmonary infiltrates, cavitation, or pulmonary effusion from the onset of mechanical ventilation > 48 hours; one or more pathogens isolated from endotracheal aspirate, bronchoscopy cultures, or lung biopsy; and at least one of the following: fever $\geq 38.5^{\circ}$ C, leukocytosis WBC $\geq 10{,}000/mm^3$, and sputum change (new onset of purulent sputum, or change in character) (Marelich et al., 2000; Zack et al., 2002).

Time on Mechanical Ventilation is measured in consecutive minutes with intubation measured as the first minute and extubation as the last minute on ventilator; i.e., if a patient is intubated on Saturday at 0210 and extubated on Monday at 0618, time on ventilator would be 52 hours and 8 minutes, or 3128 minutes.

Protocol Compliance is adherence to and utilization of the GSICU Mechanical Ventilation Weaning Protocol for those patients who meet eligibility criteria to be on the protocol. Protocol compliance will be determined by continuous adherence to the GSICU Mechanical Ventilation Weaning Protocol, and factors contributing to abatement of and adherence to the protocol will be tabulated.

Acute Physiology and Chronic Health Evaluation (APACHE) II score is a severity of disease classification system, using a point score based upon initial values of 12 routine physiologic measurements, age, and previous health status to provide a general measure of severity of disease, and prognostically stratify acutely ill patients. The score ranges from 0 to 71 (Knaus, Draper, Wagner, & Zimmerman, 1985). A modified APACHE II score is measured by utilizing the Minimum Data Set (MDS) Version 4 Illness Severity Score data points (Martin, 2002) (Appendix G).

Rapid Shallow Breathing Index is measured by attaching a hand held spirometer to the endotracheal tube and recording the respiratory rate and average tidal volume over one minute. The RSBI is calculated by dividing the respiratory rate per minute by the tidal volume in litres (Yang & Tobin, 1991).

CROP is an index based on compliance, respiratory rate, arterial oxygenation, and maximum inspiratory pressure. The CROP index is calculated by multiplying the dynamic compliance of the respiratory system by the fraction of inspiratory-effort reserve

per breath by the ratio of arterial to alveolar oxygen tension and divided by the respiratory rate. The equation is: $(C_{dyn} \times P_{I}max \times [P_aO_2/P_AO_2])/rate$ (Yang & Tobin, 1991).

Riker Sedation Agitation Scale (SAS) is a tool to monitor the patient's agitation and sedation, and includes seven levels of agitation, ranging from dangerous agitation to unarousable (Riker, Picard, & Fraser, 1999) (Appendix H).

Data Collection Procedures

Pre-intervention and Post-intervention Data Collection

Patients, pre-intervention and post-intervention, were identified within 24 hours of admission to the GSICU by the researcher to ensure the inclusion criteria were met and informed consent was obtained. Demographic data and identified clinical variables were obtained and recorded (Appendix I). On a 24-hour basis, from the time of intubation until 48 hours post-extubation, the researcher completed the Daily Data Collection Record (Appendix I) by obtaining information from the patient chart, and discussions with multidisciplinary team members at the bedside. The researcher reassessed inclusion and exclusion criteria every 24 hours. Patient data was collected daily, hand recorded on the Daily Data Collection Record (Appendix I) and entered into SPSS at the completion of the pre-intervention data collection and at the completion of the post-intervention data collection.

After completion of the pre-intervention patient data collection, GSICU staff were provided the opportunity to participate in a focus group session, to complete the Protocol Directed Weaning Survey (Appendix E), to complete the Safety Climate Survey (Appendix D), and to participate in a learning session.

Focus Group Sessions

First, staff were provided an opportunity to participate in a focus group session. The information sheet was distributed to each staff member at the start of the focus group (Appendix J), an explanation of the purpose of the focus group sessions, and what would be expected of them should they decide to participate. Staff were assured that their participation was entirely voluntary and their responses would remain anonymous. The focus group sessions were held twice daily between 1400 and 1430 and twice nightly between 2300 and 2330 for seven consecutive days. An additional focus group session was offered to the Physicians during a regularly scheduled grand rounds session. The size for each focus group was between 3 and 13 staff. At the beginning of the focus group, staff were asked to complete the Safety Climate Survey (Appendix D) and Protocol Directed Weaning Survey (Appendix E), and place it in a sealed envelope to be deposited in a box on leaving the session. The researcher guided the focus group discussion, using an outline of questions (Appendix C), to explore the implementation process of protocol directed weaning. Focus group sessions were tape recorded to assist in identification of effectors and resistors to the mechanical ventilation weaning protocol. The team attendance for the focus group sessions was 112, and the disciplines represented at these sessions were; Registered Nurses, Respiratory Therapists, Nursing Attendants, Physiotherapists, Residents, and Attending Intensivists.

Learning Sessions

Five weeks following the focus group sessions, staff were provided the opportunity to participate in a learning session. The learning sessions were held twice daily at 1400 and 1430 and twice nightly between 2300 and 2330 every day for seven

consecutive days. An additional learning session was offered to the Physicians during a regularly scheduled grand rounds session. The team attendance for the learning sessions was 101 and the disciplines represented at these sessions were; Registered Nurses, Respiratory Therapists, Nursing Attendants, Attending Intensivists, Residents, and Clinical Nurse Educators. Learning sessions included: the definition of ventilator associated pneumonia; predictors of successful weaning from mechanical ventilation; the rationale of protocol directed care; an interpretation of how to utilize the weaning protocol; and a summary of what the research is trying to accomplish (Appendix K). Opportunity to ask questions throughout the presentation and at the end of the presentation was provided.

After the completion of post-intervention patient data collection, the GSICU staff were then provided the opportunity to once again complete the Safety Climate Survey (Appendix D) and the Protocol Directed Weaning Survey (Appendix E). The team attendance for the resurvey sessions was 31 (17 [54.83%] attended the initial sessions), and the disciplines represented at these sessions were Registered Nurses and Respiratory Therapists.

Data Analysis

Descriptive statistics using frequencies, medians, means, and standard deviations were used for all data collected. To compare pre-intervention versus post-intervention outcomes of: rate of failed extubations; ventilator associated pneumonia; length of time on mechanical ventilation; multidisciplinary staff's understanding of the mechanical ventilation weaning protocol; the multidisciplinary staff's perceptions of the safety

climate; and the compliance rate of utilizing the mechanical ventilation weaning protocol, independent two-tailed t-test and Chi-square tests were conducted.

Relationships among the Acute Physiology and Chronic Health Evaluation (APACHE) II score, age, gender, reason for intubation, Riker Sedation Agitation Scale (SAS), head of bed elevation, placement of feeding tube, subglottic secretion drainage, and the outcomes of rate of failed extubations, rate of ventilator associated pneumonia, and length of time on mechanical ventilation were examined using a Chi-square test. Level of significance was $p \leq 0.05$.

Ethical Considerations

Ethical approval was obtained from the Health Research Ethics Board, University of Alberta. All patients within 24 hours of admission to the GSICU were assessed by the researcher to determine if they meet inclusion criteria. The researcher approached the subject or guardian to provide information related to the purpose of the study, and the manner in which the data would be collected (Appendix L). Subjects and their guardians were informed of the potential benefits of this study, such as knowing that their participation in this study will guide implementation of the weaning procedure or may decrease the time spent receiving mechanical ventilation. No adverse effects were associated with participation in this study. In no situation did the study protocol interfere with delivery of patient care. Subject or guardian's consent were obtained (Appendix M) and only patient chart data (Appendix I) was recorded. Subjects enrolled in this study had their privacy and confidentiality protected. The subject was assigned a case number, and the subject was identified only by this case number on all chart data collected related to the study. A list of the case study numbers corresponding to the subject's name was

maintained in an administrative office separate from the data collection. All data collected will remain locked in the researcher's office and for a minimum of five years.

Staff participation in the focus groups, learning sessions, and completion of the Safety Climate Survey and Protocol Directed Weaning Survey was voluntary. Staff were provided an information sheet (Appendix J) related to the purpose of the study, and what was expected of them should they decide to participate. Staff responses to the Protocol Directed Weaning Survey remained anonymous. At the end of each focus group and learning session, the researcher made it known to the staff that they could contact her should they have any questions or concerns related to the study.

Staff participation in research had the potential to distract from direct patient care, while at the same time had the potential to promote job satisfaction and retention of skilled health care providers. The researcher remained cognisant not to distract the staff members from priorities of patient care and this meant having to alter focus group or learning session timing depending on patient staff ratios and priorities on the unit. Communication with the Unit Managers, Respiratory Therapist Supervisor, and the Medical Director was facilitated to ensure patient care priorities were not jeopardized. When a staff member was interrupted during a focus group or learning session to attend to a patient care priority, the member was offered the option to return to the session in progress or attend an alternate session.

Focus Group Sessions

The purpose of the focus group sessions was to gain an understanding of the clinical staff's perceptions about the mechanical ventilation weaning protocol. An improvement in staff's perceptions related to a proposed change in procedural protocol

has been associated with decreases in errors, patient length of stay, and employee attrition (Sexton et al., 2003). The content analysis of the focus groups was used to make changes to the mechanical ventilation weaning protocol.

Participants' responses were broken down into four categories: awareness; strengths; limitations; and suggestions for improvements. Within each category, various labels were assigned which described clinical staff's perceptions about protocol directed weaning from mechanical ventilation. The core labels for each category are illustrated in Table 1.

Table 1
Thematic Categories and Core Labels

Category	Core Labels
Awareness	Not aware of protocol Aware of protocol Aware of protocol, via study Aware of protocol, not seen in practice
Strengths	Provides direction Provides accessibility Improves communication Provides evidence-based practice Provides autonomy
Limitations	Rigidity Inconsistent adherence Becomes outdated Induces apathy
Suggestions for Improvement	Protocol has to be simple, clear, and user friendly Make it accessible and visible to find on the unit Initiate protocol with admission Protocol must fit heterogeneous population Education on how to utilize the protocol Clarify spontaneous breathing trial means low level pressure support Ensure protocol does not require a physician's order to initiate

The first category which emerged from the focus group sessions was the clinical staff's sense of awareness of protocol directed weaning from mechanical ventilation. Their awareness was coded as: (1) not aware of the protocol; (2) aware of the protocol; (3) aware of protocol via study; (4) aware of protocol and not seen in practice.

The majority of the clinical staff indicated they were not aware of the weaning protocol, as illustrated with the following quotes:

"I have not seen anyone on the protocol"

"I have never seen protocol directed weaning done here"

"Never heard of it"

"Never used it"

"I am not aware of the protocol…we don't extubate"

"I have never seen the protocol, I don't know what it looks like;"

"I didn't know we had that protocol. That's what I mean we don't get enough info"

"Maybe the protocol got lost in the management changes"

"In a place like this, there is so much information, maybe I have seen it but I don't remember."

For others, there was an awareness of the protocol for weaning, and the responses were coded as: aware of protocol; aware of protocol via study; and aware of protocol, not seen in practice:

"We saw the protocol once and never saw it again, it is gone"

"An experience I've had about the weaning protocol is being told don't worry about the weaning protocol, the RT will look after that. That was my experience, I didn't even have an opportunity to see the protocol to know what it was or even have a chance to speak to the RT and I was told don't worry about that the RT will look after it"

"The RTs have the protocol but it is not readily available to us, we don't know about it"

"I have only heard of the protocol via the study"

"I saw the protocol sheet but I do not see it in practice"

The second category which emerged was related to the strengths of using a protocol. The strengths suggested were: (1) provides direction; (2) provides accessibility; (3) improves communication; (4) provides evidence-based practice; and (5) provides autonomy. Examples of strengths related to using a protocol are:

"Protocol directed weaning will set a safety standard, trying to do something positive, trying to prevent injury and better the situation"

"Protocol directed weaning can get you to move forward, so that you don't just stay in one place and say oh no we can't go any further"

"Protocol directed weaning is formalizing the process, allowing to go ahead without having to wait for docs"

"Protocol directed weaning will maintain a level of standardization"

"Protocol directed weaning allows more input, able to initiate care"

"We had protocol directed care at night when there was a lack of MD presence and this was a tool that our hospital used to guide safe practice for patients because there was a lack of MD presence"

"We are the ones at the bedside and we know when the patient is ready for extubation, the protocol could save us having to find a doctor to get an order"

"Protocol is always things we do and we don't always think about it but it is there to guide us, especially the new people, and for those of us who have been here for awhile we need to keep thinking about it"

"I think one part of it is that you don't want to ventilate someone for too long, so I guess the main thing is when you intubate them you have to think about weaning"

"Protocol directed weaning is something that we are suppose to follow…anybody could come on, I could come on next shift to see the step the patient is on and this is where we are going"

"It gives a sense of direction, end goal for the patient"

"It provides rules"

"The protocol provides coverage, someone can pick up care shift to shift"

"Protocol directed care enables stuff to happen faster and we do not have to wait around"

"The protocol will keep you progressing"

"Protocol directed weaning establishes the right time to wean a patient"

"Protocols can trigger to think critically and prevent adverse events, for example arrhythmias"

"The protocol could provide collaboration between the RNs and RTs to gauge patient progress and act on care"

"The protocol should have all kinds of loops, and you can go front and back to each step"

"We know we can do it, provides coverage, we know it has been researched and it works good"

"Protocols are convenient and allow people to make a judgement"

"Protocol directed weaning will provide better patient outcomes"

"We will have shorter vent time with protocol directed weaning"

"Protocol directed weaning gives one the freedom to wean"

"We will be doing less calling with protocols"

"RNs are the ones at the bedside 24 and 7 and we're the one that knows the patient so the protocol is there to make decisions moment to moment"

"If RTs and RNs have the ability with a weaning protocol then this means the go ahead to wean and extubate"

"Protocols provide continuity for patient care"

"The protocol is standard weaning. It is great to see a protocol written that way we can go to that"

The third category was related to the limitations of procedural weaning from mechanical ventilation. The main limitations identified were: (1) rigidity; (2) inconsistent adherence; (3) become outdated; and (4) induces apathy. Examples of limitations to procedural weaning from mechanical ventilation are:

> "Extubation is procedure and physician driven, patient could be doing well then all is shot to hell"
>
> "Protocol directed weaning varies from MD to MD…you know by which MD is on in the a.m. whether the patient will be extubated"
>
> "Extubation depends upon who is extubating and the day of the week"
>
> "Spontaneous breathing trial means something different to MDs for some cold neb, others bagger. The meaning of spontaneous breathing trial is not clear. There is a perception that I had to do a spontaneous breathing trial as opposed to low level pressure support. You do not need to do a spontaneous breathing trial if the pressure support is low"
>
> "Weaning and extubation is MD driven, taking the patient for tests and paralyzing is starting at square one again because we are back on a mode to control everything"
>
> "Protocols should not be in concrete, protocols should be a tool and not carved in stone"
>
> "We also have other protocols, like ACTH stimulation test, even though we have a protocol the physicians will order however they want it done. They are never going to follow what is written on a flow sheet"
>
> "Variance in practice is a question of patient safety. Sometimes you have to sedate the patient and if they are on the weaning protocol then you may have to go to assist control, the variance makes me feel unsafe"
>
> "The MDs all have different ideas. The Director should dictate some things to the unit. There are going to be some differences but this should be one thing that should be dictated. The MDs jobs are going to be different but there are some things that everyone should be the same about…Staff men are going to have different flavors and there are certain things that the Director should demand from the unit to be, certain expectations for a standard of care"
>
> "You go to them saying that the protocol has been followed and you need an order for extubation and they actually write the whole thing out. [participant in

the room asks: The protocol?]. Yes, they write the protocol out. They are taking out all your chances of having a brain. You need some sort of clinical because not everyone will handle a bagger trial. It is just frustrating that everything is taken away. You either get one who doesn't care or ones who are so anxious they write absolutely every little detail, exactly what time to take the blood gas at. Take ABG at 1018. It gets frustrating that way because there are such extremes"

"There is an attitude to let the patient rest on the ventilator and this causes a problem"

"The physicians will deter their residents from following protocol if they do not agree with it"

"A lot of times we are being told to go up and down on the PEEP and we need an order to do this…if we had protocol directed weaning then it would make it easier for us to make suggestions"

"There are times that people are ready to be extubated but for reasons of tradition, docs don't want to extubate"

"I have seen failed extubations but not related to the protocol"

"You want to know my fear, everything gets so bloody mapped out that after awhile people do not know how to think…we need less of maps and people telling you every step of the way…in this environment I don't think"

"Not extubating in the night is a tradition based on not having enough support in the hospital if something goes bad"

"We take them downstairs for tests with the tube in then we end up sedating heavily whereas if we had extubated them we could take them for the test on nasal cannula, a lot of times they say that we will wait until after the test which does not make sense if the patient is sedated"

"When the patient is ready for extubation they usually get antsy and end up being sedated. Then held back in the morning waiting for hs sedation to wear off"

"The binders are not updated"

"Like the sedation protocol, as an example, you are sitting there for half an hour trying to figure out the right drug for the patient and they are still going berserk"

"We have the little am updates, but if you are on your week off but then some people strictly work nights they miss out. There needs to be a better system of getting info to the front line workers because so often I find out things by word of mouth"

"Protocols on the unit are not updated according to the literature and do not reflect evidence based medicine"

"It is too easy just to write down numbers, unfortunately we get lax…having a protocol is not going to make it any less busy"

"The variance with physicians is confusing"

"For awhile we attempted to follow then reverted back to our old practices, I don't know why"

"We are chronically short of RTs especially on nights and say someone has sats of 99, you know their oxygen can be dropped and their respiratory rate is 8, you know their pressure support can be dropped, and you call them but they are so busy with six million other things that they don't possibly get a chance to come around for an hour and a half, until the next monitoring time. A lot of times lately it seems that the RTs are flat out and don't have the resources or they are too busy doing procedures, bronch, bronch, bronch, trach, trach, trach. So they don't have an opportunity to be at the bedside so when it comes to weaning that is not done…The nurse should be able to reduce the pressure support when the RTs aren't around;"

"I've heard some talk not from the physicians but other disciplines that they have no desire to follow any type of protocol, that a protocol can't cover every patient and a protocol is not the way to go and they have no intention in following it"

"It's like doing cardiac outputs at 2 o'clock in the morning but no one is looking at them until 10 o'clock in the morning, what's the value"

Finally, the fourth category was suggestions for improvement. Suggestions for improvement were:

"Put the protocol in admission orders"

"The protocol has to be endorsed"

"Provide the protocol"

"We need education about the protocol so that the protocol will be successful"

"No pocket cards about the protocol"

"If it is not easy to follow then it won't be done"

"I want the protocol to give us autonomy, to be proactive and assertive so our profession can make changes"

"Protocols have to be utilized at the bedside"

"Protocols have to be revisited and reviewed"

"Somebody needs to spearhead the protocol…"

"We have to be committed to the protocol, constantly have reminders, always have to be thinking about it"

"Make sure the protocol fits a heterogeneous population"

"Protocols, there should be more inservices, they didn't really tell us how to use the protocol"

"We need a form to track weaning from shift to shift so we can see what they did on the last shift. We need documentation to see if the protocol is being followed, this should be on the RT board"

"Protocol directed weaning has to be on the top of the scale here as importance. The worst thing for a patient has to be lying in the bed unable to communicate. That has got to be the most uncomfortable thing, especially if the patient is awake and alert"

"Check the binders routinely to make sure binder is up to date;"

"We have to be able to find the protocol, it has to be accessible"

"Everybody has to be educated, not just one quarter of the staff for consistency"

"MDs have to be educated if we are going to implement a protocol, everybody has to be on board not just half of them, or one doing it their way or another doing it another way"

"We need communication and trust one another in clinical judgement to achieve protocol directed weaning"

"Spontaneous breathing needs to be defined with the doctors. They thought it meant a T-piece trial. We were taking a lot of extra steps…clarify spontaneous breathing trial with the docs"

"Weaning should be part of the bedside RNs responsibility. It is a patient need"

"Protocol directed weaning should be initiated between the RN and RT"

"We should have a kardex stating daily goals including weaning and the protocol"

"Regular inservices on weaning patients is needed"

"The team has to see the end goal for the patient as being the same in order to work off the same page"

"I would like someone to show me the weaning protocol and say this is what we expect, I am not aware of it"

"Protocol directed weaning should be a standard of practice and expectation on the unit"

"Protocol directed weaning should be initiated any time of the day"

"Discuss the protocol at beside rounds with all disciplines, especially the dieticians because if the patient is extubated it changes the way we feed them"

"The protocol must be visible"

"Have the protocol on the chart and RT board"

"A protocol has to have flexibility"

"We need a quick reference so you don't have to go shuffling through a big binder looking for it. Put it on the chart"

"We need constant reminders to use the protocol"

"Have the protocol available to everyone"

"We need to communicate the reasons why we do not use the protocol"

"I don't think our residents know they should be inserviced"

The feedback from the focus groups was then used to make the following changes to the implementation of the mechanical ventilation weaning protocol: omit the idea of posting the protocol on the computer screens at the patient bedside; omit the idea of providing pocket size copies of the protocol; ensure daily that the protocol is accessible with the patient's chart, specifically the respiratory board, during learning sessions, and survey sessions; post a sign at the entrance of the respiratory station reminding the

respiratory therapists to utilize the protocol; hang the protocol on the walls during the learning sessions; amend the initial step of the protocol from 'medical treatment optimized' to 'reversal of underlying cause'; collaborate with the radiology department to have chest radiographs accessible early in the morning for any patients identified as being ready for extubation; exclude those patients receiving mechanical ventilation via tracheostomy intubation; and collaborate with the respiratory therapist supervisor with respect to these changes.

Additionally, the following instructions and clarification were given: the protocol starts with admission, and is utilized continuously throughout the day; a physician's order is not required to initiate the protocol; apply the protocol on all patients except those receiving mechanical ventilation via tracheostomy; how to access the protocol, and if the protocol is not accessible in the protocol binder or on the RT board, a copy would be available in the RT station; respiratory therapists in collaboration with the registered nurses would be initiating the protocol; document when the protocol is and is not initiated, and the reasons why the protocol cannot be followed; the protocol is the standard of practice and expectation of the GSICU; and a low level of pressure support is a spontaneous breathing trial. The staff were guided through the protocol, highlighting the most crucial aspects, and provided an interpretation of how to use the protocol.

CHAPTER FOUR

Findings

The purpose of this study was to assess the outcomes before and after an implementation program for a mechanical ventilation weaning protocol with a heterogeneous adult critical care population in the GSICU at the University of Alberta Hospital. The outcomes assessed were: rate of failed extubations; rate of ventilator associated pneumonia; length of time on mechanical ventilation; multidisciplinary staff's understanding of the mechanical ventilation weaning protocol; multidisciplinary staff's perceptions of the safety climate; and compliance rate of utilizing the mechanical ventilation weaning protocol. The usual staffing ratio of nurse to patient was 1:1, although this ratio varied depending on staffing availability, census on the unit, and severity of patient illness. The usual staffing ratio of physician to patients was 1:3, although this ratio varied depending on physician availability, and census on the unit.

Study Enrollment

A total of 392 patients were admitted to the GSICU during the study periods: 228 during the pre-intervention period, and 164 during the post-intervention period (Figure 1). A consecutive sample of 203 patients (103 pre-intervention, 100 post-intervention) were enrolled over a five month period. Enrollment for the pre-intervention period commenced on November 7, 2003 and concluded on January 31, 2004. Enrollment for the post-intervention period commenced on March 12, 2004 and concluded on April 28, 2004 (Figure 1).

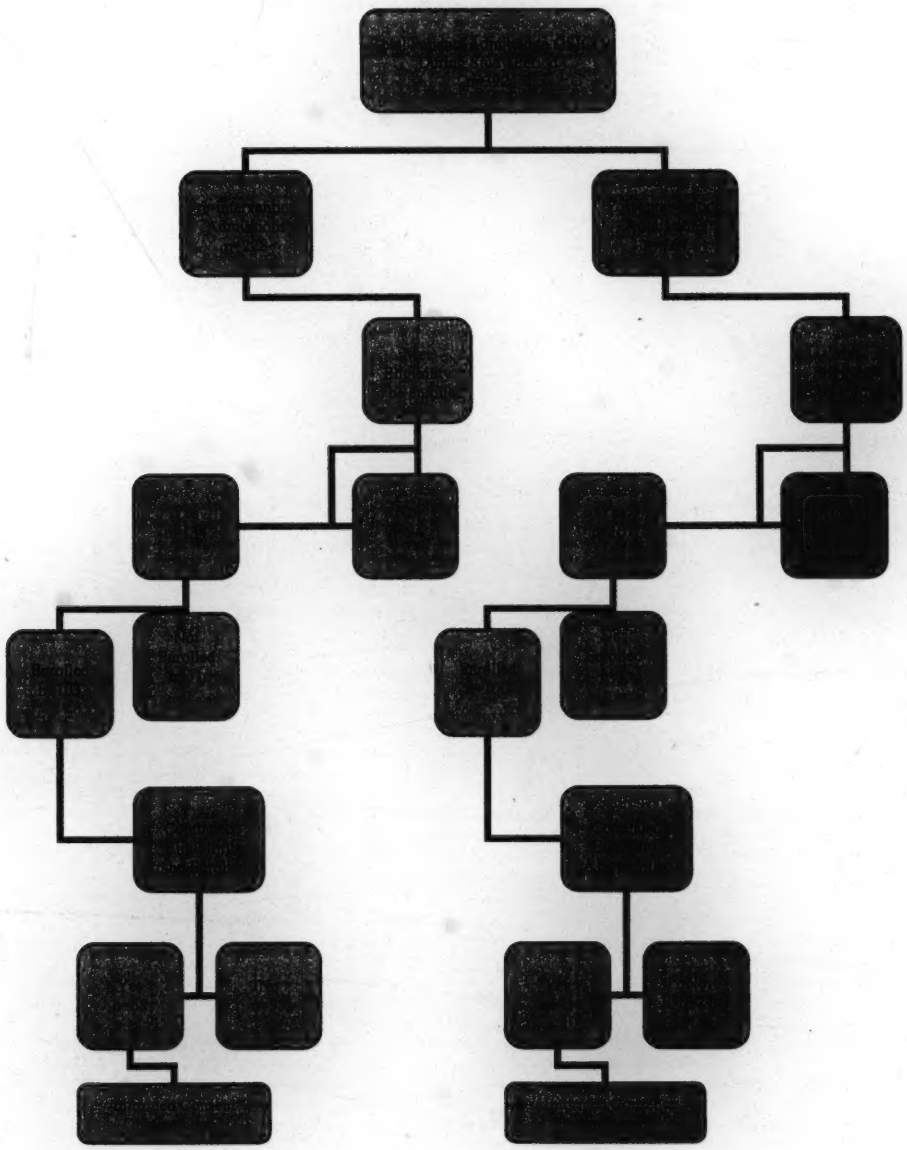

Figure 1. Study Enrollment

During the pre-intervention period there were 228 patients admitted to the GSICU; 134 patients were eligible for the study, and 94 patients were ineligible. The 31 patients eligible but not enrolled were for the following reasons: enrolled in another study (n=21); unable to obtain an informed consent (n=2); not assessed by the researcher prior to extubation (n=3); and not assessed within 24 hours of admission (n=5). The 94 patients who were not eligible for the study were for the following reasons: not receiving mechanical ventilation via endotracheal or tracheostomy (n=53); diagnosed with ARDS (n=3); extubated within the last 48 hours (n=5); laryngeal disease (n=6); receiving mechanical ventilation via tracheostomy (n=5); weaning from mechanical ventilation was not a goal; i.e., the philosophy of care was to withdraw or withhold curative organ therapy (n= 12); not assessed by the researcher prior to extubation (n=6); discharged from the unit prior to being assessed by the researcher (n=2); and transferred to another intensive care unit (n=2).

Of the 103 patients eligible and enrolled in the study in the pre-intervention period, 35 patients became ineligible for the following reasons: weaning from mechanical ventilation was not a goal; i.e., the philosophy of care was to withdraw or withhold curative organ therapy (n=20); enrolled in another study (n=4); receiving mechanical ventilation via tracheostomy intubation (n=4); unable to obtain informed consent within 24 hours of admission (n=4); those patients being transferred to another intensive care unit (n=2); and those patients or families who withdrew consent (n=1). Of the 68 enrolled in the study with continued eligibility, the researcher was not able to obtain an informed consent with 5 patients for the following reasons: those patients not oriented to place or time (n=2); those patients who died > 48 hours after extubation

(n=1); those patients who left hospital against medical advise, and unable to be contacted by telephone after discharge (n=1); and those patients who declined (n=1).

During the post-intervention period there were 164 patients admitted to the GSICU; 101 patients were eligible for the study, and 63 patients were ineligible for the study. Of the 101 patients eligible for the study, 1 patient was not enrolled due to being extubated prior to being assessed by the researcher, and 63 patients were not eligible for the study for the following reasons: extubated within the last 48 hours (n=10); laryngeal disease (n=6); the philosophy of care was to withdraw curative organ therapy (n=7); receiving mechanical ventilation via tracheostomy (n=10); not receiving mechanical ventilation (n=28); and discharged prior to being assessed by the researcher (n=2).

Of the 100 patients eligible and enrolled in the study in the post-intervention period, 27 patients became ineligible for the following reasons: those patients with laryngeal disease (n=1); weaning from mechanical ventilation was not a goal: i.e., the philosophy of care was to withdraw or withhold curative organ therapy (n=14); those patients extubated within the last 48 hours (n=1); receiving mechanical ventilation via tracheostomy intubation (n=7); and those patients diagnosed with ARDS (n=4). Of the 73 enrolled in the study with continued eligibility, the researcher was not able to obtain an informed consent with 7 patients for the following reasons: those patients who declined (n=5); and those patients who asked for time to think about participation and then were discharged from hospital, and unable to be contacted by telephone after discharge (n=2). Thus, the final sample consisted of 63 patients in the pre-intervention, and 66 patients in the post-intervention group, for a total sample size of 129 patients.

Characteristics of the Sample

The characteristics of the total sample (n=129) receiving mechanical ventilation in the GSICU are summarized in Table 2. There were no statistically significant differences between the pre-intervention and post-intervention groups on demographic characteristics. The total sample was predominately male (n=83, 64.4%), with the majority between 51 to 80 years of age (n=81, 62.7%). The total number of smokers at intubation was 16 (12.4%).

All comorbidities were collected on each patient, and the priority comorbidity was recorded as the one comorbid health problem for purposes of analysis. Group difference in the priority comorbid health problem was not significant ($p = 0.985$). The priority comorbidities for the majority of the patients in both the pre-intervention and post-intervention groups were cardiovascular disease (pre-intervention group, n=24; post-intervention group, n=14), endocrine disease (pre-intervention group, n=22; post-intervention group, n=10), and mental illness (pre-intervention group, n=21; post-intervention group, n=10). Other comorbid health problems included: neurological/trauma (pre-intervention group, n=4; post-intervention, n=4); respiratory disease (pre-intervention group, n=8; post-intervention, n=8); gastrointestinal disease (pre-intervention group, n=5; post-intervention, n=5); renal disease (pre-intervention group, n=1; post-intervention, n=2); cancer (pre-intervention group, n=1; post-intervention, n=3); infectious disease (pre-intervention group, n=3; post-intervention, n=5); muscoskeletal disease (pre-intervention group, n=3; post-intervention, n=2); and unknown (pre-intervention group, n=4; post-intervention, n=4).

The majority of the patients in both the pre-intervention (17.5%) and post-intervention groups (15.2%) were admitted to the GSICU for neurological and trauma reasons (pre-intervention group, n=11; post-intervention group, n=10). Other admitting diagnoses included: congestive heart failure (pre-intervention, n=1; post-intervention, n=0), chronic obstructive pulmonary disease (pre-intervention, n=5; post-intervention, n=6), asthma exacerbation (pre-intervention, n=1; post-intervention, n=1), pneumonia (pre-intervention, n=3; post-intervention, n=2), renal failure (pre-intervention, n=1; post-intervention, n=3), liver disease (pre-intervention, n=2; post-intervention, n=0), gastrointestinal disease (pre-intervention, n=4; post-intervention, n=9), cancer (pre-intervention, n=1; post-intervention, n=3), overdose (pre-intervention, n=3; post-intervention, n=4), transplantation (pre-intervention, n=3; post-intervention, n=3), sepsis (pre-intervention, n=8; post-intervention, n=1), and other states (pre-intervention, n=20; post-intervention, n=24). There were no significant differences between groups with respect to admitting diagnosis ($p = 0.358$).

An Acute Physiology and Chronic Health Evaluation (APACHE) II score was performed on all patients within 24 hours of admission to the GSICU. Five patients were intubated greater than 24 hours of admission (pre-intervention n=3; post-intervention n=2). The minimum APACHE II score in the pre-intervention group was 10 and 6 in the post-intervention group. The maximum APACHE II score in the pre-intervention group was 38 with a mean of 20.81 ± 7.00, and 37 with a mean of 20.21 ± 7.62 in the post – intervention group. There were no statistically significant differences between groups in APACHE II scores ($p=0.644$).

Table 2
Characteristics of the Sample

Variable	Total		Pre-intervention		Post-intervention		pValue
	n	%	n	%	n	%	
Gender	129		63		66		0.462
Female	46	35.6	20	31.7	26	39.4	
Male	83	64.4	43	68.3	40	60.6	
Age	129		63		66		0.664
18-31	14	10.8	8	12.7	6	9.1	
31-40	13	10.0	8	12.7	5	7.6	
41-50	22	17.0	8	12.7	14	21.2	
51-60	23	17.8	12	19.0	11	16.7	
61-70	23	17.8	13	20.6	10	15.2	
71-80	25	19.3	10	15.9	15	22.7	
81-90	9	7.0	4	6.3	5	7.6	
Smoker	129		63		66		0.291
Yes	16	12.4	10	15.9	6	9.1	
No	19	14.7	11	17.5	8	12.1	
Unknown	94	72.9	42	66.7	52	78.8	
Priority Comorbid Health Problem	129		63		66		0.985
Neurological/Trauma	8	6.2	4	6.3	4	6.1	
Cardiovascular Disease	24	18.6	14	22.2	10	15.2	
Respiratory Disease	16	12.4	8	12.7	8	12.1	
Gastrointestinal Disease	10	7.8	5	7.9	5	7.6	
Renal Disease	3	2.3	1	1.6	2	3.0	
Endocrine Disease	22	17.1	10	15.9	12	18.2	
Mental Illness	21	16.3	10	15.9	11	16.7	
Cancer	4	3.1	1	1.6	3	4.5	
Infectious Disease	8	6.2	3	4.8	5	7.6	
Muscoskeletal Disease	5	3.9	3	4.8	2	3.0	
Unknown	8	6.2	4	6.3	4	6.1	
Admitting Diagnosis	129		63		66		0.358
CHF	1	0.8	1	1.6	0	0	
COPD	11	8.5	5	7.9	6	9.1	
Asthma Exacerbation	2	1.5	1	1.6	1	1.5	
Pneumonia	5	3.9	3	4.8	2	3.0	
Renal Failure	4	3.1	1	1.6	3	4.5	
Liver Disease	2	1.5	2	3.2	0	0	
GI Disease	13	10.1	4	6.3	9	13.6	
Cancer	4	3.1	1	1.6	3	4.5	
Overdose	7	5.4	3	4.8	4	6.1	
Neurological/Trauma	21	16.3	11	17.5	10	15.2	
Transplant	6	4.7	3	4.8	3	4.5	
Sepsis	9	6.9	8	12.7	1	1.5	
Other	44	34.1	20	31.7	24	36.4	
APACHE II	129		63		66		0 .644
Mean±SD			20.81±7.00		20.21±7.62		

Clinical Status on Intubation

Table 3 summarizes the clinical status of the patients on intubation. There were no statistically significant differences between the pre-intervention and post-intervention groups in clinical status on intubation. The reasons for intubation were similarly distributed between the pre-intervention and post-intervention groups. The reasons were respiratory failure (pre-intervention, n=24; post-intervention, n=18), pre-operative intubation (pre-intervention, n=17; post-intervention, n=21), airway protection (pre-intervention, n=20; post-intervention, n=21), and other (pre-intervention, n=2; post-intervention, n=5). Other reasons for intubation were: combativeness; intubated at the request of ICU; intubated for status epilepticus; intubated for patient agitation and delirium; and intubated for desaturation.

Patients were intubated with either an endotracheal tube or subglottic secretion drainage using an EVAC™ endotracheal tube manufactured in St. Louis, Missouri by Mallinckrodt Incorporated. The EVAC™ endotracheal tube incorporates a separate lumen ending into the subglottic area for drainage of secretions. The type of intubation tube passed depended on the decision of the respiratory therapist assisting with the intubation. All patients intubated prior to admission to the GSICU; i.e., in the field, emergency department, or operating suite, were intubated with an endotracheal tube.

Arterial blood gas sampling was performed on 124 patients (96.1%) within 24-hours of intubation. A normal pH was recorded on 26 of the patients (43.3%) in the pre-intervention group, and 41 of the patients (64.1%) in the post-intervention group. A normal partial pressure of arterial CO_2 was recorded with 30 of the patients (50%) in the pre-intervention group, and 35 of the patients (54.7%) in the post-intervention group. A

partial pressure of arterial oxygenation of 60 or greater was recorded on 57 of the patients (95%) in the pre-intervention group, and 63 of the patients (98.4%) in the post-intervention group.

Arterial oxygen saturation with intubation was greater than 90% in most cases for the pre-intervention (n=61; 96.8%) and post-intervention groups (n=64; 98.5). Hemoglobin levels were greater than 90 mmol/Litre in 42 patients (67.7%) of the pre-intervention group and n=46 (69.7%) of the post-intervention group.

The $PaFiO_2$ ratio and minute ventilation, both potential predictors of successful weaning from mechanical ventilation, were comparable across groups. The $PaFiO_2$ ratio was greater than 200 in 85 patients (pre-intervention, n=37; and post-intervention, n=48); and the minute ventilation was less than 10 in 89 patients (pre-intervention, n=41; and post-intervention, n=48).

The respiratory rate was comparable between the two groups at intubation. The respiratory rate was documented hourly on the nursing flowchart. For those patients who had fluctuations in their respiratory rate, the modal rate was recorded. In the pre-intervention group, 23 patients (36.5%) had a respiratory rate between 10 and 14 breaths per minute (bpm), and 20 patients (31.7%) had a respiratory rate between 15 and 19 bpm. One patient had a respiratory rate less than 10 bpm, and one patient had a respiratory rate between 30 and 35 bpm. In the post-intervention group, 20 patients (30.3%) had a respiratory rate between 10 and 14 bpm, and 30 patients (45.5%) had a respiratory rate between 15 and 19 bpm. No patients had a respiratory rate less than 10 bpm or between 30 and 35 bpm.

Table 3
Clinical Status on Intubation

Variable			Total	Pre-intervention		Post-intervention		pValue
			n	n	%	n	%	
Reason for Intubation			129	63		66		0.459
	Respiratory Failure		42	24	38.1	18	27.3	
	Pre-operative Intubation		38	17	27.0	21	31.8	
	Airway Protection		41	20	31.7	21	33.3	
	Other		7	2	3.2	5	7.6	
Type of Endotracheal Tube			129	63		66		0.357
	ETT		118	56	88.9	62	93.9	
	EVAC™		11	7	11.1	4	6.1	
ABG	PH		124	60		64		0.068
		<7.35	33	20	33.3	13	20.3	
		7.35-7.45	67	26	43.3	41	64.1	
		>7.45	24	14	23.3	10	15.6	
		Missing	5	3		2		
	PaCO2		124	60		64		0.660
		<35	40	19	31.7	21	32.8	
		35-45	65	30	50.0	35	54.7	
		>45	19	11	18.3	8	12.5	
		Missing	5	3		2		
	PaO2		124	60		64		0.349
		<60	4	3	5.0	1	1.6	
		60-80	21	10	16.7	11	17.2	
		81-100	43	24	40.0	19	29.7	
		>100	56	23	38.3	33	51.6	
		Missing	5	3		2		
SaO_2 (%)			128	63		65		0.488
	<90		3	2	3.2	1	1.5	
	>90		125	61	96.8	64	98.5	
	Missing		1	0		1		
Hgb (g/L)			126	62		64		0.725
	<70		6	2	3.2	4	6.3	
	70-80		9	5	8.1	4	6.3	
	81-90		23	13	21.0	10	15.6	
	>90		88	42	67.7	46	71.9	
$PaFiO_2$ (mmHg)			118	57		63		0.389
	<200		33	19	33.3	14	22.2	
	>200		85	37	64.9	48	76.2	
	Unknown		11	1	1.8	1	1.6	
MV (l/min)			125	60		65		0.459
	<10		89	41	68.3	48	73.8	
	10-14		29	15	25.0	14	21.5	
	15-19		5	2	3.3	3	4.6	
	>19		2	2	3.3	0	0	
	Missing		4	3		1		
RR (bpm)			129	63		66		0.445
	<10		1	1	1.6	0	0	
	10-14		43	23	36.5	20	30.3	
	15-19		20	20	31.7	30	45.5	
	20-24		31	17	27.0	14	21.2	
	25-29		3	1	1.6	2	3.0	
	30-35		1	1	1.6	0	0	
	35		0	0	0	0	0	

Ventilation Parameters on Intubation

The mode of ventilation and ventilatory parameters on intubation varied considerably but were comparable between the pre-intervention and post-intervention groups (Table 4). On admission to the GSICU, 17 patients (13.1%) received assist control ventilation, 13 patients (10.1%) received pressure control ventilation, 50 patients (38.7%) received pressure support ventilation, 5 patients (3.8%) received spontaneous breathing ventilation, and 44 patients (34.1%) received other modes of mechanical ventilation which included PRVC, VC, and CMV.

The PEEP on intubation was recorded as either between 5 to 10 cmH_2O, or between 11 to 15 cmH_2O for all patients at intubation. No patients had a PEEP less than 5 cmH_2O or greater than 15 cmH_2O after intubation (Table 3).

Comparable across both groups, more than 50% of the patients (71/129) had a FiO_2 of less than or equal to 0.40, and 8.5% of the patients (11/129) had high FiO_2 levels, greater than 0.70. In the pre-intervention group, 8 patients (12.7%) had a FiO_2 less than 0.35; and 25 patients (39.7%) had a FiO_2 between 0.35 and 0.40. In the post-intervention group, 15 patients (22.7%) had a FiO_2 less than 0.35; and 23 patients (34.8%) had a FiO_2 between 0.35 and 0.40 (Table 3).

Table 4
Ventilation Parameters on Intubation

Variable	Total n	Pre-intervention n	%	Post-intervention n	%	pValue
Mode of Ventilation	129	63		66		0.205
AC	17	8	12.7	9	13.6	
PCV	13	5	7.9	8	12.1	
PSV	50	24	38.1	26	39.4	
T-piece	2	0	0	2	3.0	
CPAP	3	0	0	3	4.5	
Other	44	26	41.3	18	27.3	
Positive End Expiratory Pressure (cmH_2O)	127	63		64		0.800
<5	0	0	0	0	0	
5-10	109	55	87.3	54	84.4	
11-15	18	8	12.7	10	15.6	
>15	0	0	0	0	0	
Missing	2	0		2		
Fractional Inspired Oxygen (%)	129	63		66		0.471
<35	23	8	12.7	15	22.7	
35-40	48	25	39.7	23	34.8	
41-50	28	13	20.6	15	22.7	
51-60	11	4	6.3	7	10.6	
61-70	8	5	7.9	3	4.5	
71-80	5	3	4.8	2	3.0	
81-90	1	1	1.6	0	0	
91-100	5	4	6.3	1	1.5	

Clinical Practices Illustrated Over Time

Ventilation Parameters

Ventilation parameters assessed included mode of ventilation, positive end expiratory pressure, and fractional inspired oxygen. Changes in ventilatory parameters were recorded on the respiratory flow sheet, and collected daily. The daily pre-intervention and post-intervention changes in ventilation parameters are illustrated at Figures 2 to 7. On day 1 of ventilation the majority of the pre-intervention group were ventilated with 'other' which included, PRVC, VC, CMV (pre-intervention, 41.3%); whereas the majority of the post-intervention group were ventilated with the pressure support mode (post-intervention, 39.4%). By day 2 of ventilation the majority of the sample were ventilated with the pressure support mode (pre-intervention, 65.5%; post-

intervention, 73.1%). The most frequently utilized mode of ventilation in both groups was pressure support. Figures 4 and 5 illustrate changes in positive end expiratory pressure for the pre-intervention and post-intervention groups. On day 1 of ventilation the majority of the patients in both groups were ventilated with a positive end expiratory pressure between 5 and 10 cm H_2O (pre-intervention 87.3%; post-intervention, 84.4%). The changes in fractional inspired oxygen during ventilation for the pre-intervention and post-intervention groups are illustrated in Figures 6 and 7.

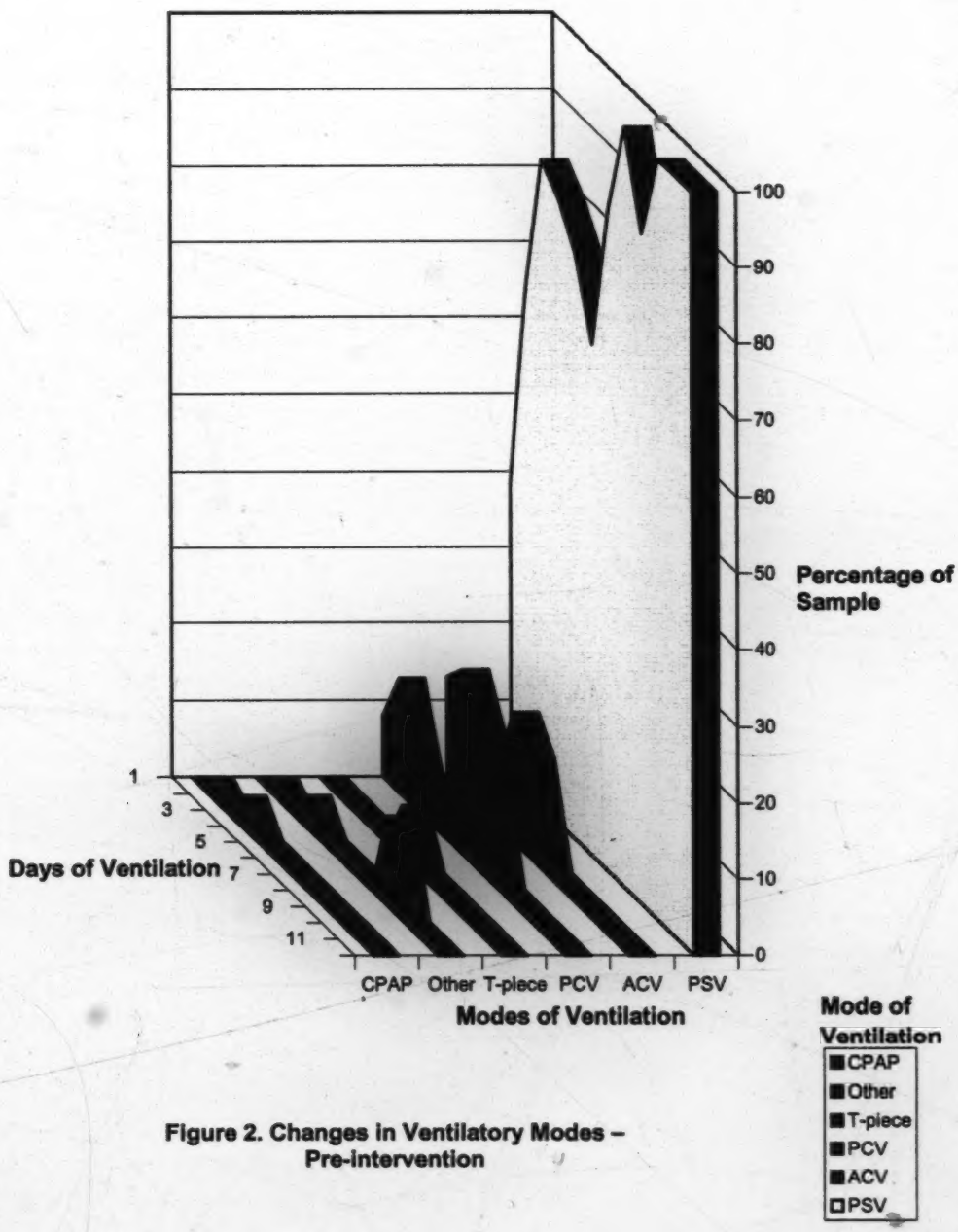

Figure 2. Changes in Ventilatory Modes – Pre-intervention

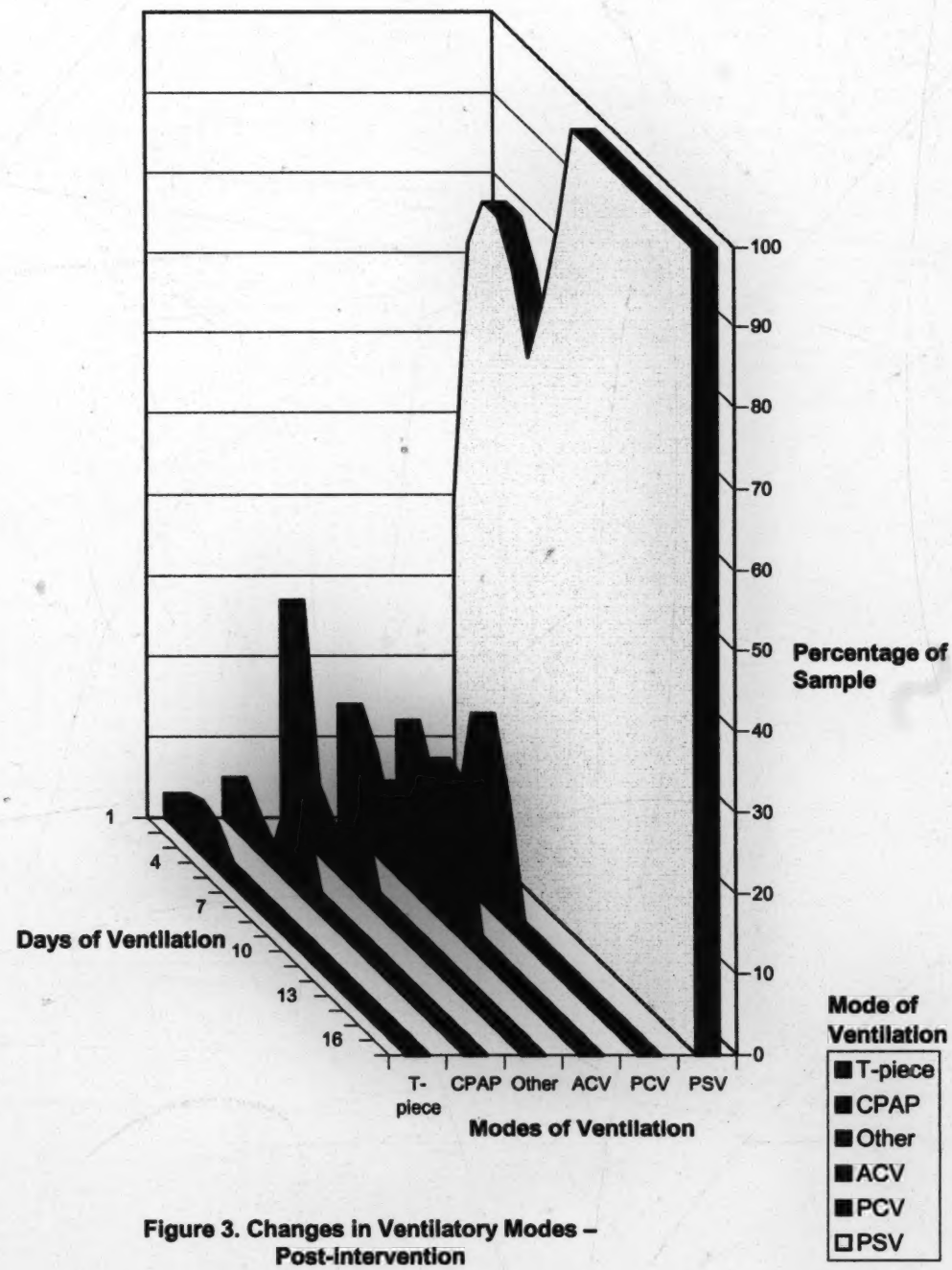

Figure 3. Changes in Ventilatory Modes – Post-Intervention

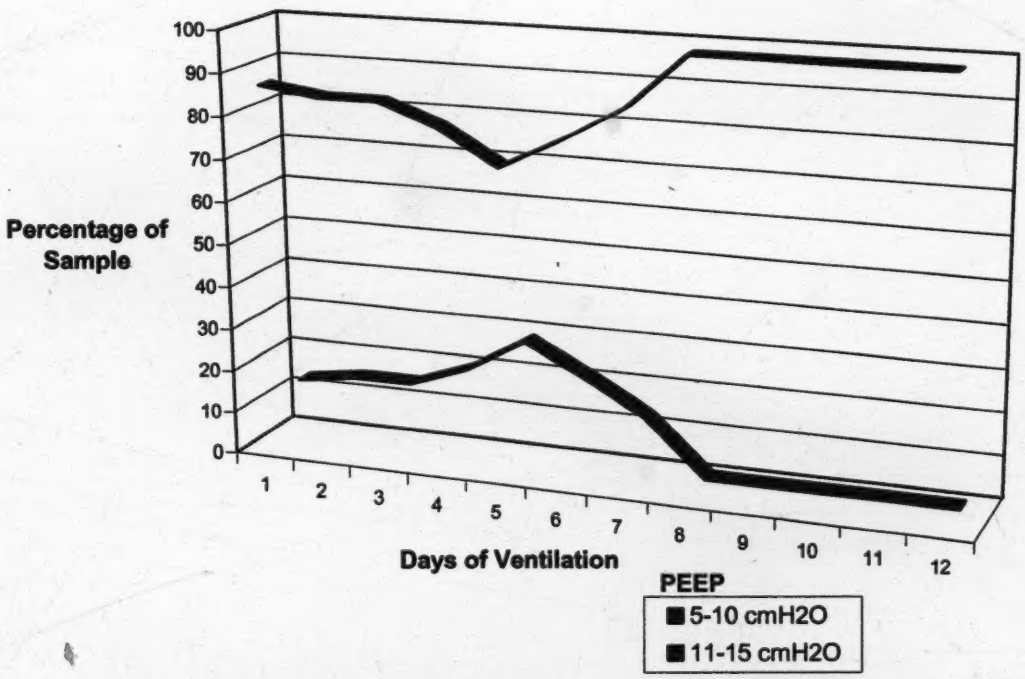

Figure 4. Changes in Positive End Expiratory Pressure During Ventilation - Pre-intervention

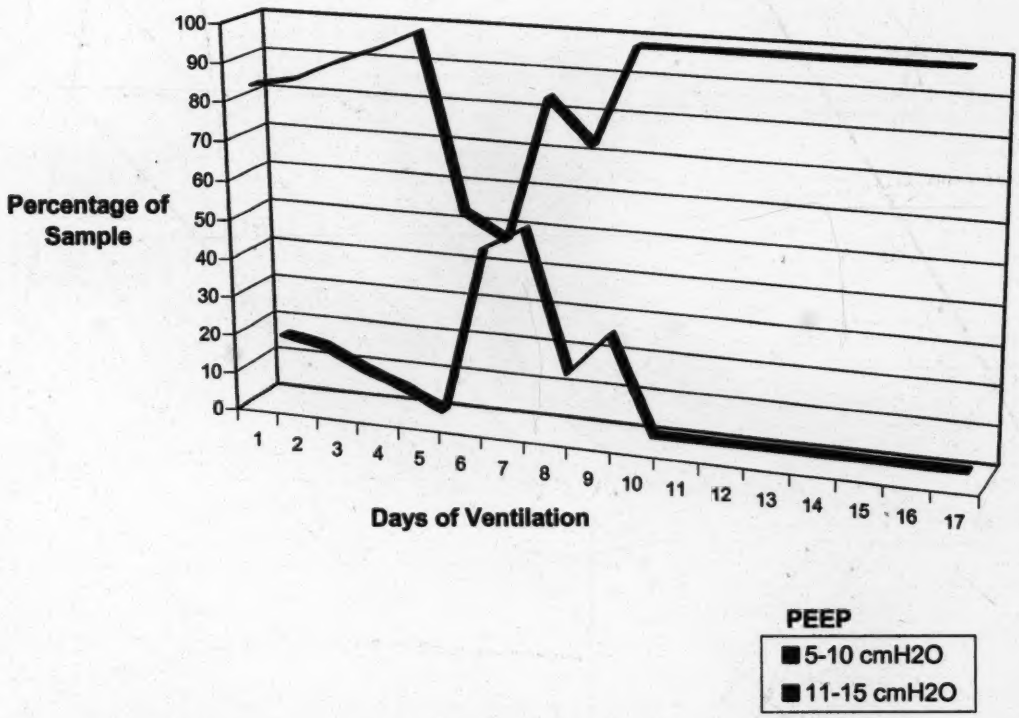

Figure 5. Changes in Positive End Expiratory Pressure During Ventilation - Post-intervention

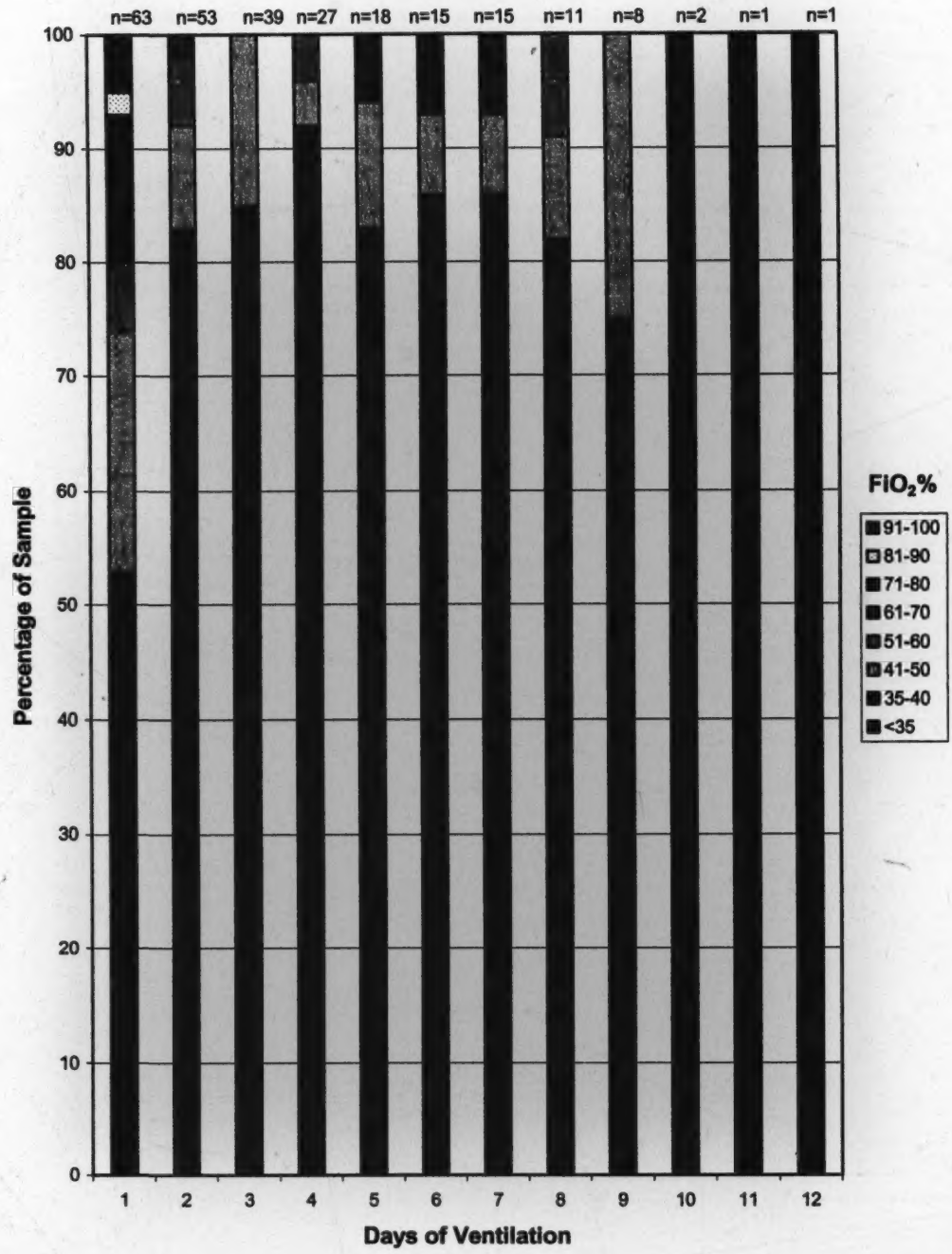

Figure 6. Changes in Fractional Inspired Oxygen During Ventilation - Pre-intervention

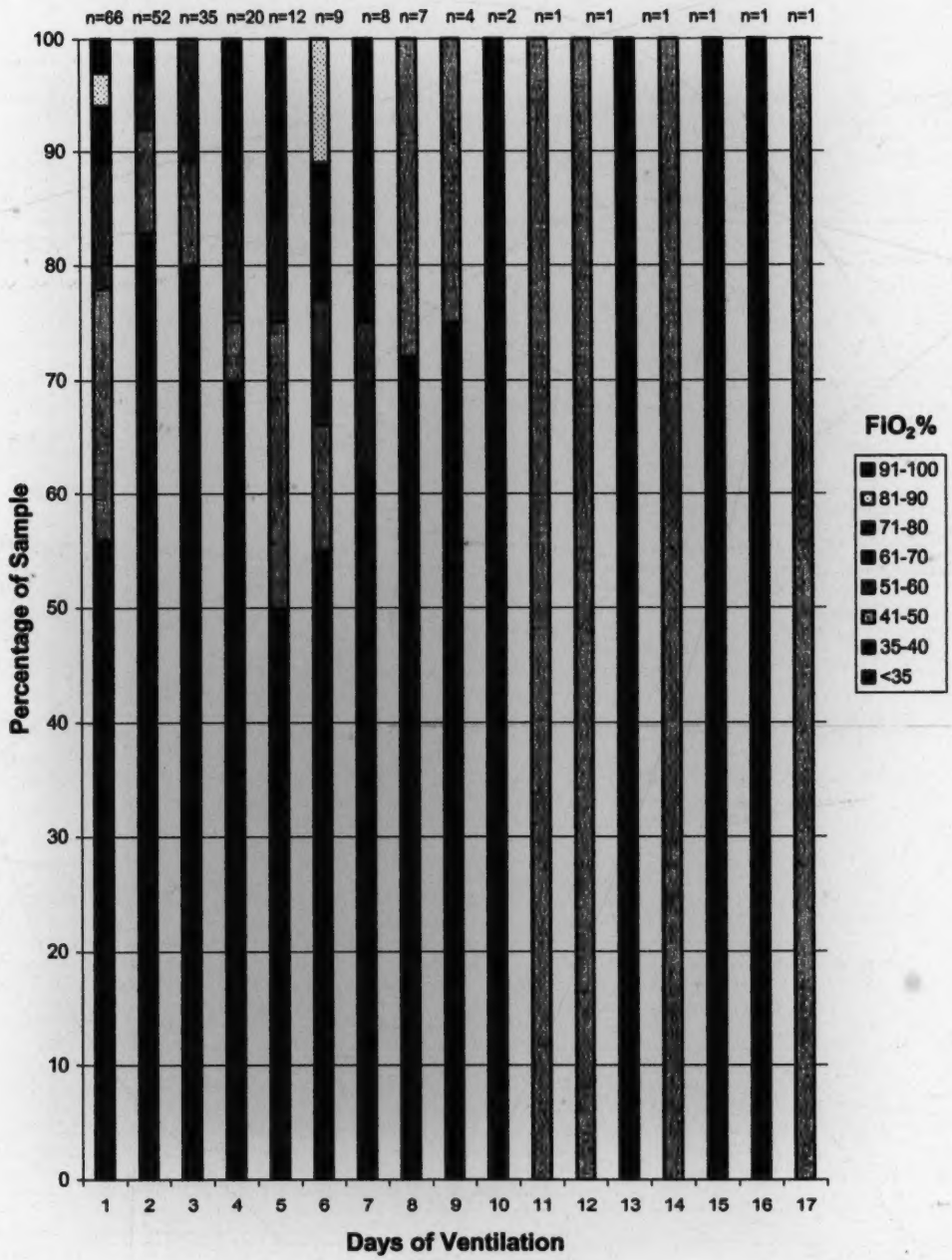

Figure 7. Changes in Fractional Inspired Oxygen During Ventilation - Post-intervention

Sedation Analgesia Paralytic Profile

The Riker Sedation Agitation Scale (SAS) is a tool to monitor the patient's agitation and sedation, and includes seven levels of agitation, ranging from dangerous agitation to unarousable (Riker et al., 1999). The SAS was not routinely recorded on the patient's health record. The SAS were comparable between the pre-intervention and post-intervention groups (Table 5). A run chart displays the mean SAS, pre-intervention versus post-intervention over time, and is illustrated at Figure 8. The mean SAS was higher in the post-intervention group as compared to the pre-intervention group on day 1 of ventilation (pre-intervention, 3.52 ± 1.07; post-intervention, 4.26 ± 1.70, $p = 0.028$). The mean SAS decreased on days 2 to 4 in the post-intervention group compared to the pre-intervention group, and reached a peak mean on day 7 of ventilation (pre-intervention, 4.00 ± 0.47; post-intervention, 6.50 ± 4.95, $p=0.605$). On days 10 thru 17 there was no SAS recorded in at least one of the pre-intervention or post-intervention groups.

The administration of analgesia, sedation and paralytics was recorded daily. The practice of administering analgesia, sedation and paralytics is displayed over time on run charts as a percentage of ventilated patients (Figures 9, 10, and 11). On day 1 of ventilation, the percentage of patients who received analgesia (pre-intervention, 57%; post-intervention 55%), analgesic drips (pre-intervention, 27%; post-intervention 24%), sedatives (pre-intervention, 54%; post-intervention, 44%), and paralytics (pre-intervention, 15%; post-intervention, 11%) was less in the post-intervention group as compared to the pre-intervention group ($p=0.860$, $p=0.840$, $p=0.293$, $p=0.561$, respectively). The percentage of patients who received a sedative drip (pre-intervention, 19%; post-intervention, 24%) was less in the pre-intervention group as compared to the

post-intervention group (p=0.526). By day 8 of ventilation, no sedative drips were administered in either group. By day 7 of ventilation, no paralytics were administered in the pre-intervention group, compared to the post-intervention group in which no paralytics were administered by day 8 of ventilation.

Table 5
Riker Sedation Agitation Scale (SAS)

SAS	Ventilation Day	n	Mean ± Std. Deviation	pValue
preintervention	1	44	3.52 ± 1.07	**0.028**
postintervention		27	4.26 ± 1.70	
preintervention	2	41	3.93 ± 1.01	0.963
postintervention		23	3.91 ± 1.35	
preintervention	3	27	3.67 ± 0.96	0.450
postintervention		12	3.42 ± 0.90	
preintervention	4	18	3.50 ± 1.04	0.726
postintervention		6	3.33 ± 0.82	
preintervention	5	13	3.31 ± 1.18	0.056
postintervention		5	4.00 ± 0.00	
preintervention	6	8	4.00 ± 0.93	0.630
postintervention		4	3.75 ± 0.50	
preintervention	7	10	4.00 ± 0.47	0.605
postintervention		2	6.50 ± 4.95	
preintervention	8	7	3.71 ± 0.76	0.926
postintervention		3	3.67 ± 0.58	
preintervention	9	5	3.80 ± 0.45	
postintervention		0		
preintervention	10	1	4.00	
postintervention		0		
preintervention	11	1	3.00	
postintervention		0		
preintervention	12	1	4.00	
postintervention		0		
preintervention	13	0		
postintervention		0		
preintervention	14	0		
postintervention		1	3.00	
preintervention	15	0		
postintervention		0		
preintervention	16	0		
postintervention		1	4.00	
preintervention	17	0		
postintervention		0		

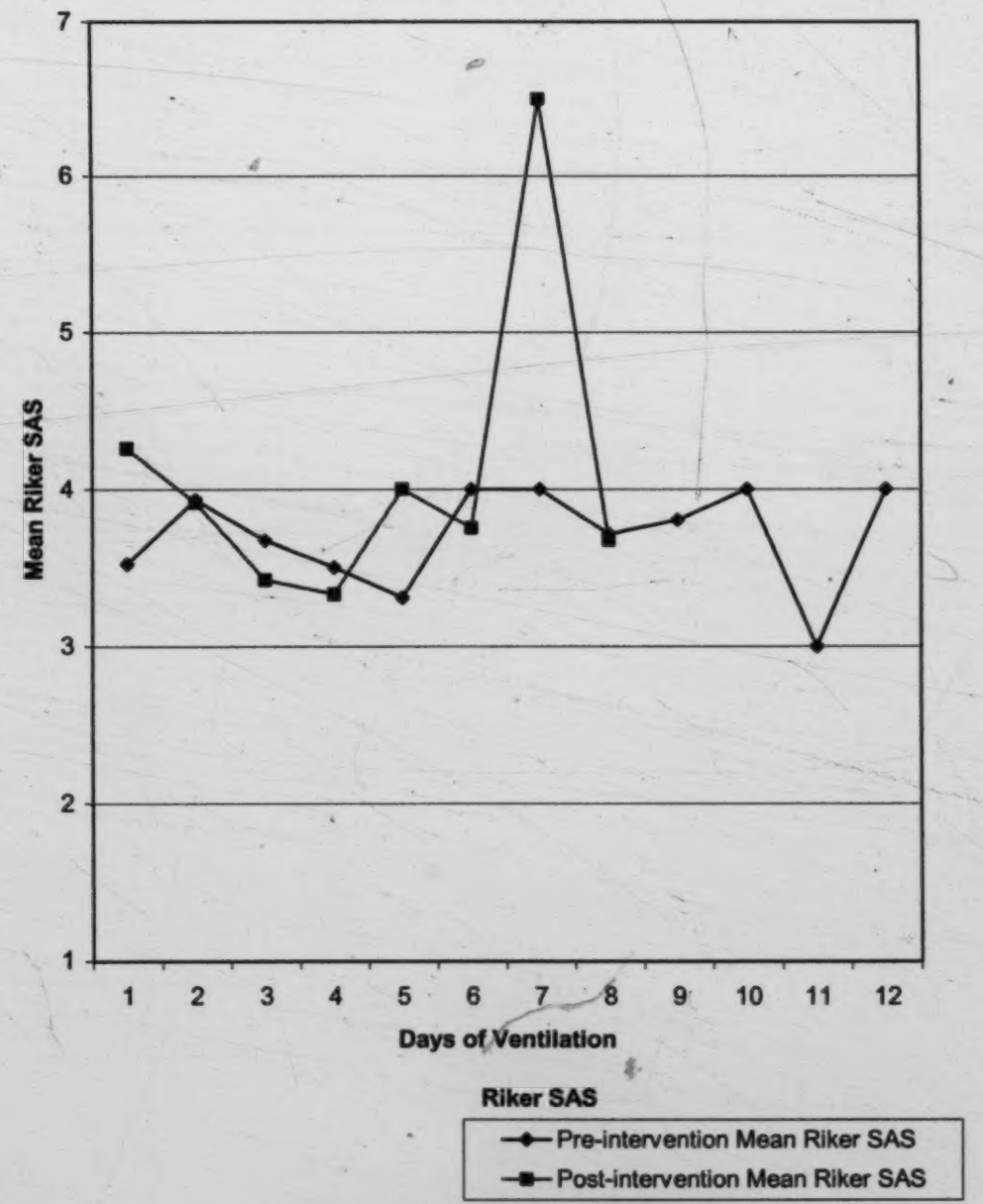

Figure 8. Riker Sedation Agitation Scale
Pre-intervention Versus Post-intervention

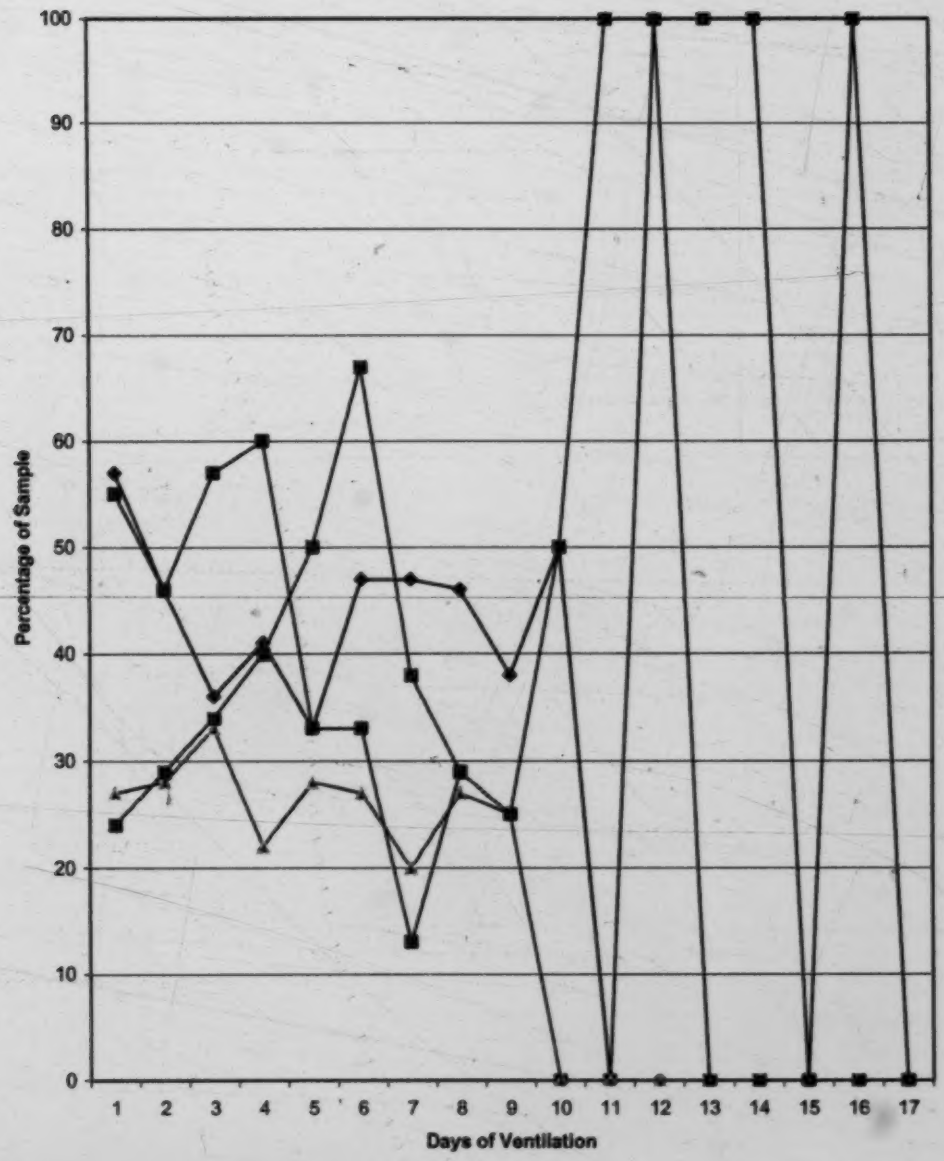

Figure 9. Practice of Analgesia Pre-intervention Versus Post-intervention

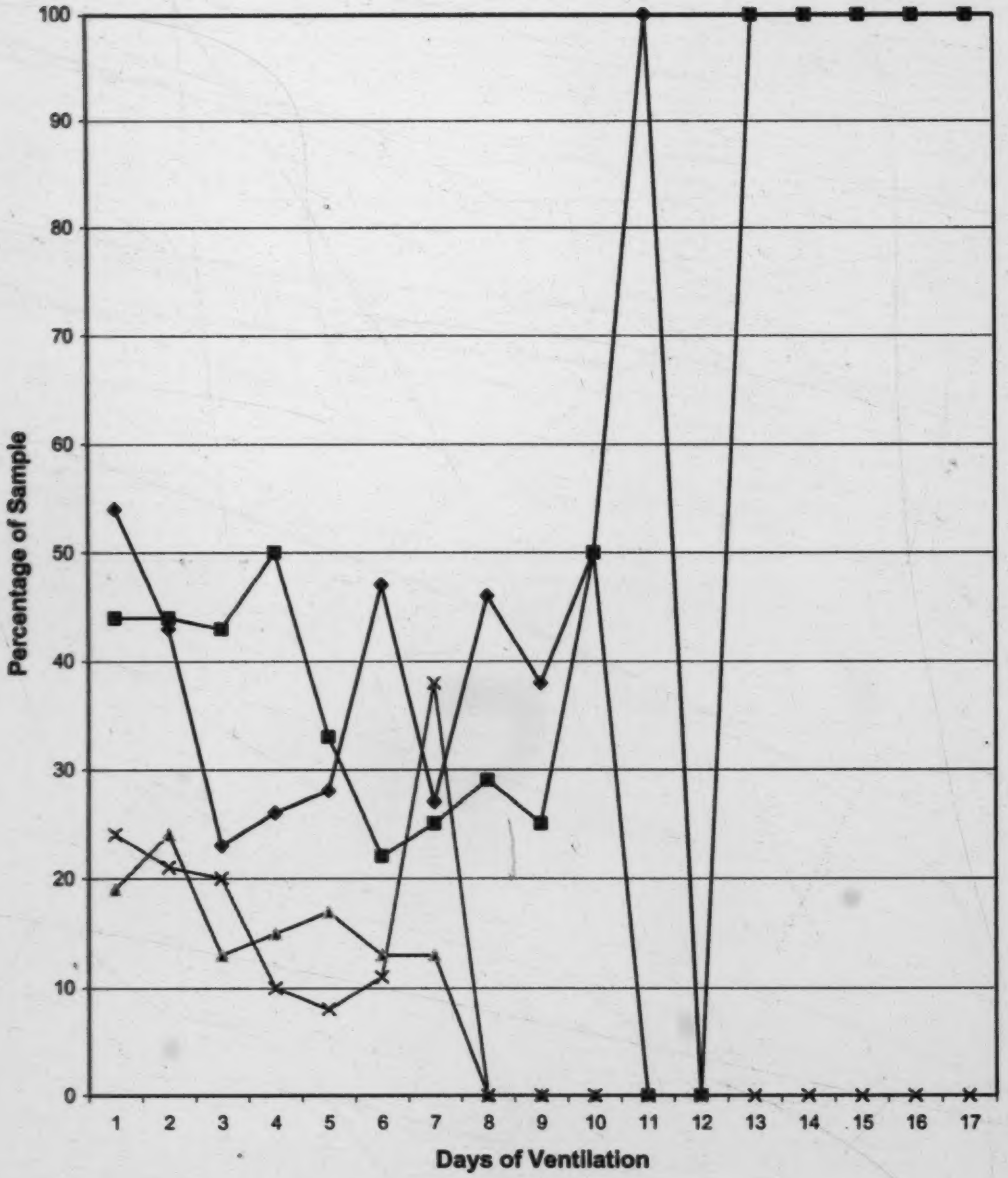

Figure 10. Practice of Sedation
Pre-intervention Versus Post-intervention

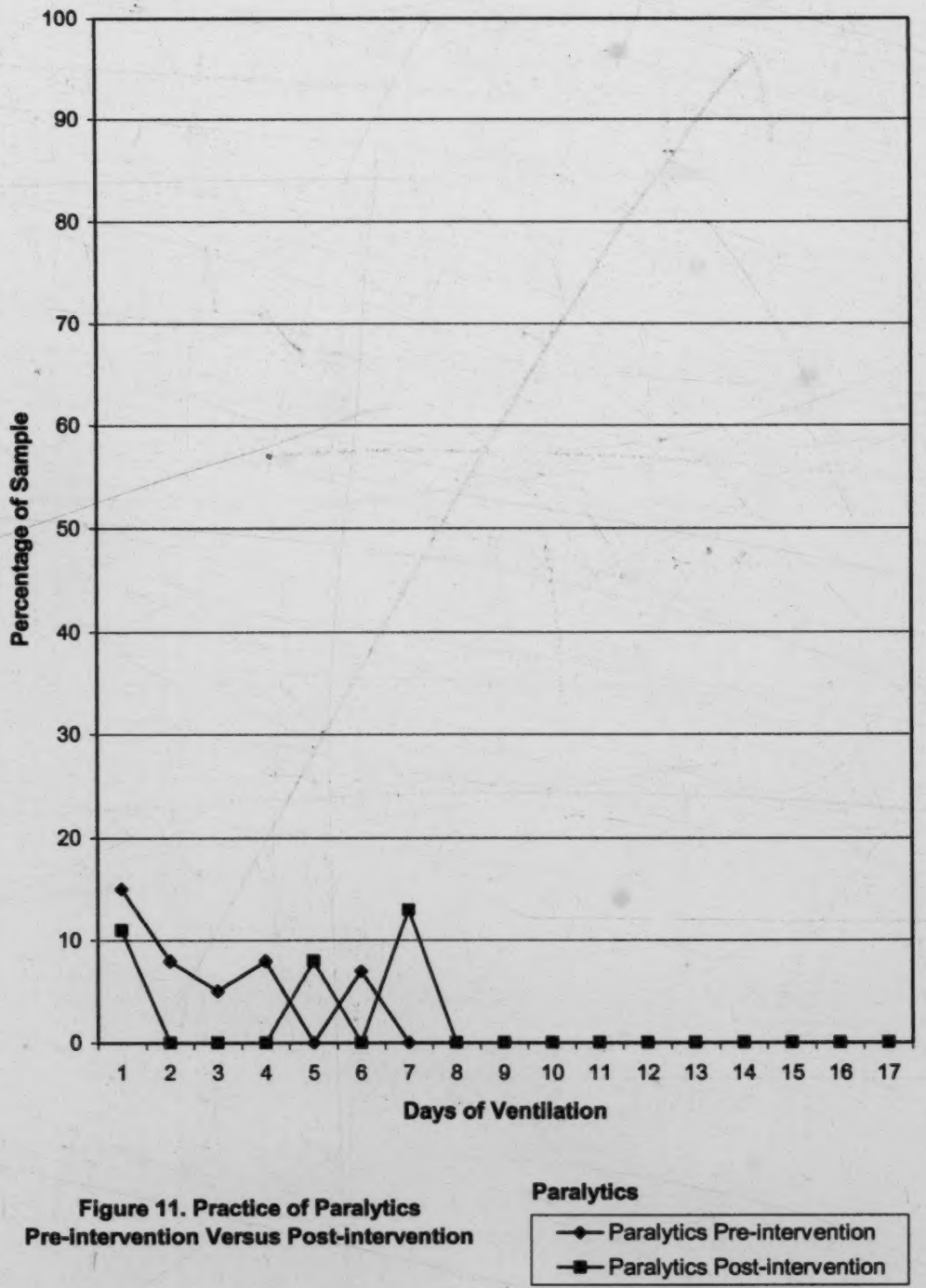

Figure 11. Practice of Paralytics Pre-intervention Versus Post-intervention

Head of Bed Elevation

Head of bed elevation (HOB) was measured with a geometric scale permanently attached to the bedside, and recorded daily as either less than 30 degrees, greater than 30 degrees, or on spinal precautions. Table 6 illustrates HOB elevation for the pre-intervention and post-intervention groups. HOB elevation was consistently greater than 30 degrees in the pre-intervention group than in the post-intervention group on days 2, 3, and 4 of ventilation ($p=0.024$, 0.006, 0.051, respectively). The pre-intervention versus post-intervention differences of HOB elevation over time are illustrated in Figure 12.

Table 6
Head of Bed Elevation

Ventilation Day	HOB Elevation	Pre-intervention (n)	Post-intervention (n)	pValue
1	< 30 degrees	37	48	0.108
	> 30 degrees	21	17	
	spinal precautions	5	1	
2	< 30 degrees	26	34	**0.024**
	> 30 degrees	22	18	
	spinal precautions	6	0	
3	< 30 degrees	16	26	**0.006**
	> 30 degrees	20	9	
	spinal precautions	4	0	
4	< 30 degrees	11	15	**0.051**
	> 30 degrees	14	5	
	spinal precautions	2	0	
5	< 30 degrees	10	10	0.332
	> 30 degrees	6	2	
	spinal precautions	1	0	
6	< 30 degrees	4	7	0.066
	> 30 degrees	9	2	
	spinal precautions	1	0	
7	< 30 degrees	6	6	0.204
	> 30 degrees	8	2	
	spinal precautions	0	0	
8	< 30 degrees	3	5	0.168
	> 30 degrees	7	2	
	spinal precautions	1	0	
9	< 30 degrees	2	2	0.576
	> 30 degrees	5	2	
	spinal precautions	0	0	
10	< 30 degrees	2	1	0.248
	> 30 degrees	0	1	
	spinal precautions	0	0	
11	< 30 degrees	1	1	
	> 30 degrees	0	0	
	spinal precautions	0	0	
12	< 30 degrees	0	1	0.157
	> 30 degrees	1	0	
	spinal precautions	0	0	
13	< 30 degrees	0	1	
	> 30 degrees	0	0	
	spinal precautions	0	0	
14	< 30 degrees	0	1	
	> 30 degrees	0	0	
	spinal precautions	0	0	
15	< 30 degrees	0	1	
	> 30 degrees	0	0	
	spinal precautions	0	0	
16	< 30 degrees	0	1	
	> 30 degrees	0	0	
	spinal precautions	0	0	
17	< 30 degrees	0	1	
	> 30 degrees	0	0	
	spinal precautions	0	0	

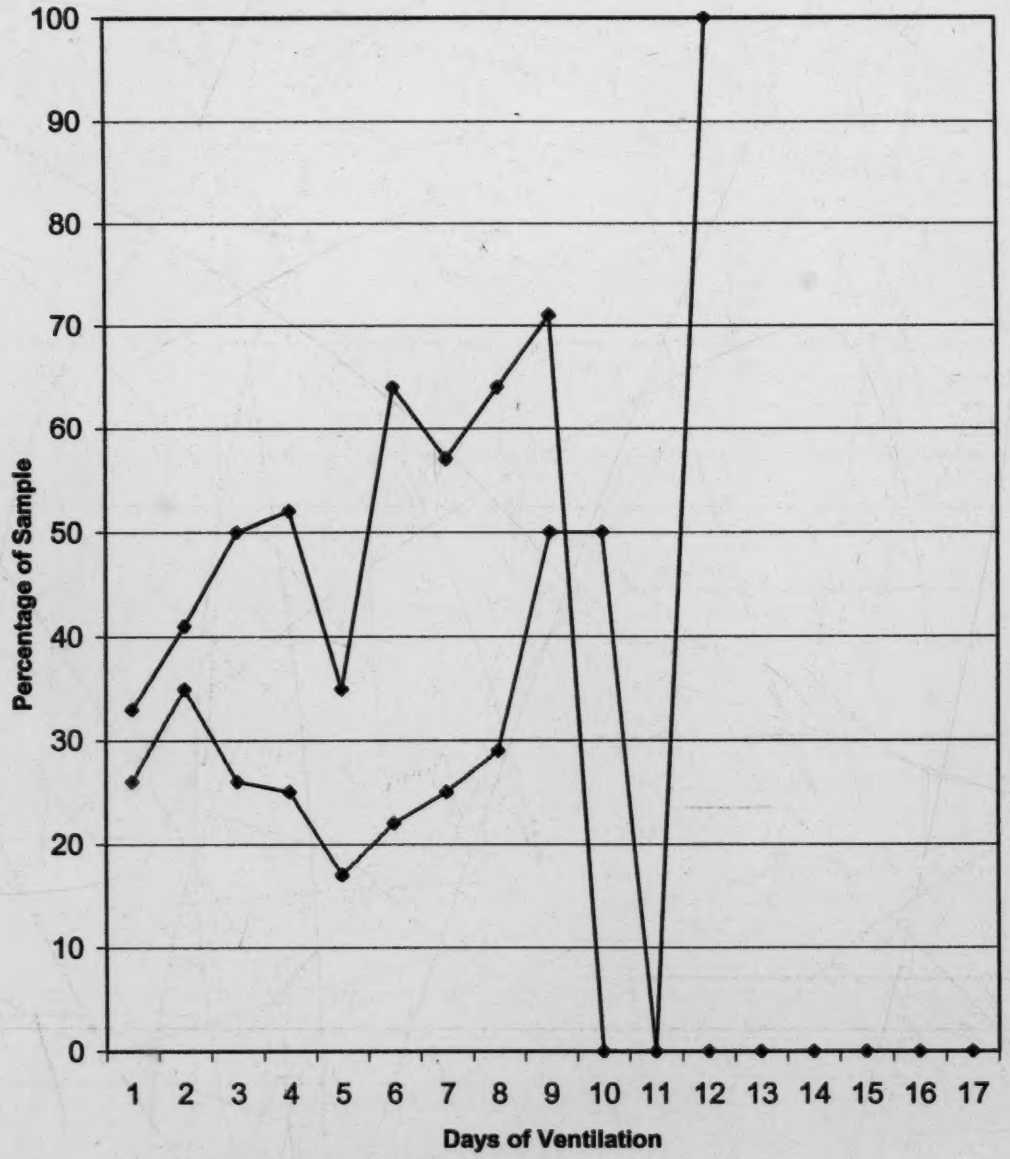

Figure12. HOB Elevation > 30 Degrees Pre-intervention Versus Post-intervention

Post Pyloric Feeding

The presence of a small bowel feeding tube or total parental nutrition was recorded daily. Chest radiographs were performed daily at the patient's bedside with the patient usually in the supine position, and the radiographs were interpreted and reported by radiologists. The radiologists usually commented on the anatomical position of the small bowel feeding tube. At the completion of each group's data collection, the radiologist's written reports were reviewed by the researcher to determine whether the patient's feeding tube was post-pyloric. Abdominal flat plates were not routinely performed for confirmation of post-pyloric feeding at initiation, or to monitor for migration of tubes. The number of patients fed with a post-pyloric feeding tube is illustrated in Table 7. The pre-intervention versus post-intervention differences of post-pyloric feeding tube placement over time is illustrated in Figure 13.

Table 7
Post Pyloric Feeding

Ventilation Day	Post pyloric feeding	Pre-intervention (n)	Post-intervention (n)	pValue
1	Yes	2	0	0.237
	No	61	66	
	TPN	0	0	
2	Yes	3	0	0.243
	No	51	52	
	TPN	0	0	
3	Yes	1	0	1.000
	No	39	35	
	TPN	0	0	
4	Yes	3	4	0.500
	No	23	16	
	TPN	1	0	
5	Yes	3	2	0.707
	No	14	10	
	TPN	1	0	
6	Yes	0	1	0.172
	No	12	8	
	TPN	3	0	
7	Yes	0	1	0.230
	No	13	7	
	TPN	2	0	
8	Yes	0	1	0.389
	No	11	6	
	TPN	0	0	
9	Yes	0	1	0.333
	No	8	3	
	TPN	0	0	
10	Yes	0	1	1.000
	No	2	1	
	TPN	0	0	
11	Yes	0	0	
	No	1	1	
	TPN	0	0	
12	Yes	0	0	
	No	1	1	
	TPN	0	0	
13	Yes	0	0	
	No	1	1	
	TPN	0	0	
14	Yes	0	0	
	No	1	1	
	TPN	0	0	
15	Yes	0	0	
	No	1	1	
	TPN	0	0	
16	Yes	0	0	
	No	1	1	
	TPN	0	0	
17	Yes	0	0	
	No	1	1	
	TPN	0	0	

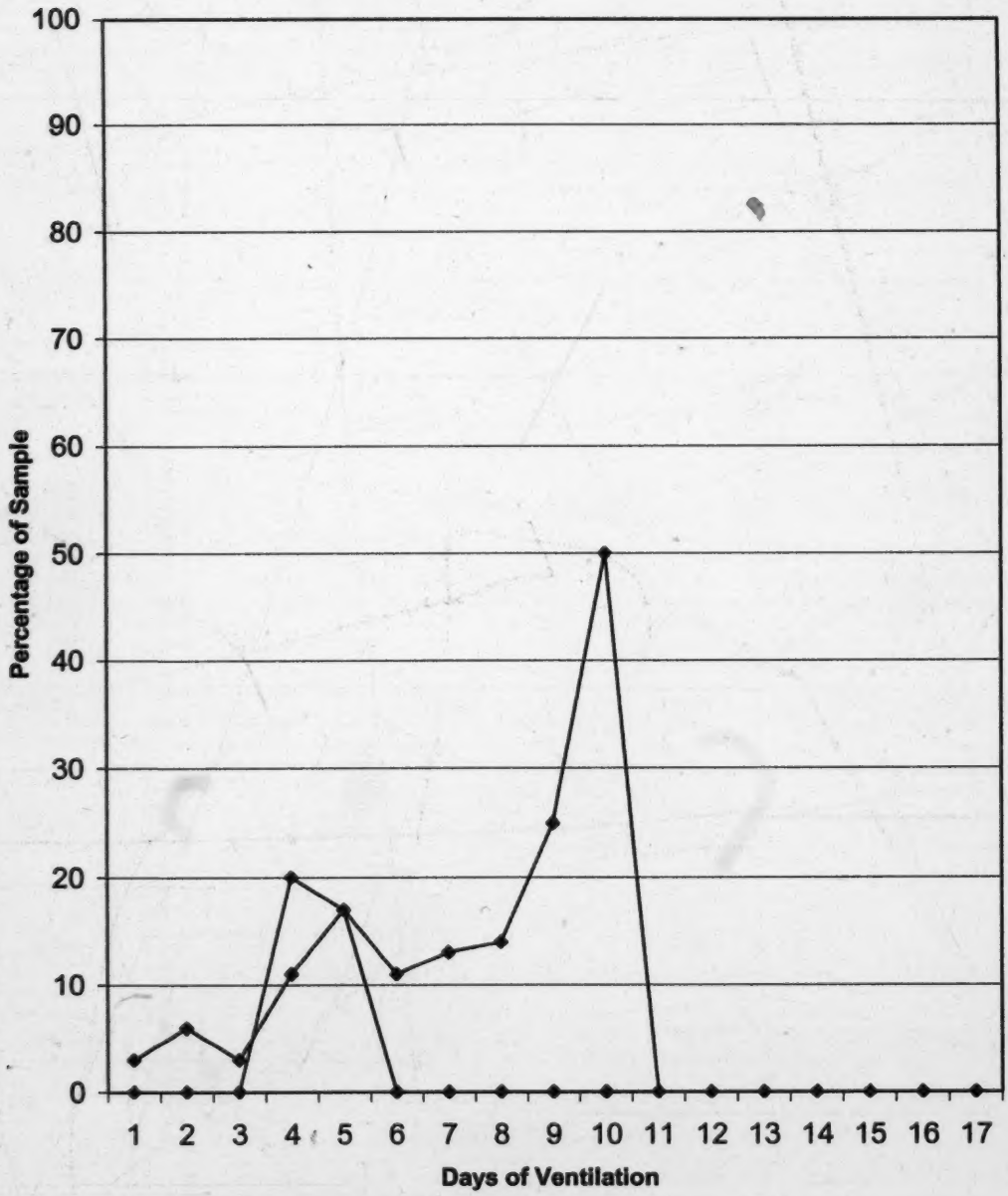

Figure 13. Post-pyloric Feeding
Pre-intervention Versus Post-intervention

Clinical Outcomes

Table 8 summarizes the clinical outcomes of this study: rate of failed extubations; rate of ventilator associated pneumonia; and length of time on mechanical ventilation.

Rate of Failed Extubations

Failed extubation was defined as reintubation within 48 hours of tracheal decannulation as a result of one or more of the following: inability to protect airway; need for broncopulmonary toilet; unable to clear secretions; PaO_2 <70% on 50% oxygen or <55% on room air; $PaCO_2$ > 55 mmHg; pH < 7.25; CO_2 narcosis; cardiac arrest; or respiratory arrest. The rate of failed extubations was 12.7% (n=8) in the pre-intervention group versus 3.1% (n=2) in the post-intervention group (p=0.051) (Table 8).

Rate of Ventilator Associated Pneumonia

Ventilator Associated Pneumonia (VAP) was defined as the occurrence of progressive or new radiographic pulmonary infiltrates, cavitation, or pulmonary effusion from the onset of mechanical ventilation > 48 hours; one or more pathogens isolated from endotracheal aspirate, bronchoscopy cultures, or lung biopsy; and at least one of the following: fever $\geq 38.5^{\circ}$ C, leukocytosis WBC $\geq 10{,}000/mm^3$, and sputum change (new onset of purulent sputum, or change in character) (Marelich et al., 2000; Zack et al., 2002). Chest radiographs were performed daily at the patient's bedside with the patient usually in the supine position, and the radiographs were interpreted and reported by radiologists. At the completion of each group's data collection, the radiologist's reports were reviewed by the researcher to determine a positive or negative chest radiograph. Tracheal tube pathogens were isolated from aspirate or bronchoscope and were not

consistently cultured. The patient's body temperature was obtained by tympanic membrane thermometer and recorded routinely. The presence of elevated white blood cells was recorded daily. The onset and character of sputum was recorded daily on the respiratory flow sheets, and interpreted daily by the researcher. Patients who received mechanical ventilation for < 48 hours did not meet the criteria for ventilator associated pneumonia (pre-intervention, n=21; post-intervention, n=29) and were not reviewed. There were 22 patients in the pre-intervention group who acquired ventilator associated pneumonia and 13 patients in the post-intervention group (p= 0.143) (Table 8).

The Centers for Disease Control and Prevention recommends two formulas in computing the rate of ventilator associated pneumonia (US Department of Health and Human Services, 1992). The first formula divides the number of patients with ventilator associated pneumonia by the number of mechanical ventilator days used and multiplies this by 1000 to obtain rate as incidence per 1000 ventilator days. The second formula divides the number of patients with VAP by the number of patients at risk; i.e., all patients ventilated > 48 hours to obtain the rate as a percentage of patients. Table 9 illustrates the rate as incidence per 1000 ventilator days, and rate as a percentage of patients. The incidence of ventilator associated pneumonia per 1000 ventilator days was 107.8 in the pre-intervention group and 78.3 in the post-intervention group. The rate as a percentage of patients was 52.4% in the pre-intervention group and 35.1% in the post-intervention group. The rate of VAP may be overestimated due to the inclusion of pulmonary effusions alone, and/or *Candida albicans* alone. With these exclusions, the rate of VAP pre-intervention was (18/42) 42.86% and (8/37) 21.62% post-intervention.

Type of Endotracheal Tube

A total of 11 of the 129 patients (pre-intervention, n=7; post-intervention, n=4) were intubated with an EVAC™ tube that incorporates a separate lumen ending into the subglottic area for drainage of secretions. There were 3 patients with an EVAC™ tube (pre-intervention, n=3) who received mechanical ventilation for <48 hours, therefore did not meet the criteria for ventilator associated pneumonia, and were not reviewed. There were 8 patients with an EVAC™ tube (pre-intervention, n=4; post-intervention, n=4) who received mechanical ventilation for > 48 hours; 5 (62.5%) of these patients (pre-intervention, n=4; post-intervention, n=1) acquired ventilator associated pneumonia; and 3 (37.5%) of these patients (post-intervention, n=3) did not acquire ventilator associated pneumonia.

Pathogens

The types of pathogens isolated from aspirate or bronchoscopy were: yeast; *Candida albicans*; *Pseudomonas*; *Enterococcus*; *Staphylococcus aureus*; *Haemophilus influenza*; *Klebsiella*; *Streptococcus agalactiae* Group B; *Streptococcus pyogenes*; and *Serratia marcescens*. Yeast was isolated the majority of the time and ranged daily from 28.6% to 50% in the pre-intervention group and 20% to 60% in the post-intervention group. The next most commonly isolated pathogen was *Candida albicans* and ranged daily from 4.2% to 20% in the pre-intervention group and 10% to 44.4% in the post-intervention group. The least commonly isolated pathogens were *Klebsiella*, *Pseudomonas* and *Serratia*. *Klebsiella* was isolated in 4 patients (pre-intervention, n=3; and post-intervention, n=1). *Pseudomonas* was isolated in 2 pre-intervention. There was

no *Pseudomonas* isolated in the post-intervention group. *Serratia marcescens* was isolated in 2 patients (pre-intervention, n=1; post-intervention, n=1).

Length of Time on Mechanical Ventilation

Time on mechanical ventilation was measured in consecutive minutes with intubation or the establishment of an airway by means of an endotracheal tube as the first minute on the ventilator, and extubation or the removal of the endotracheal tube as the last minute on the ventilator. The minimum time receiving mechanical ventilation in the pre-intervention group was 215±4078.612 and 575±4050.903 minutes in the post-intervention group. The maximum time receiving mechanical ventilation in the pre-intervention group was 14855 minutes with a mean of 5162.76±4078.612 minutes in the pre-intervention group, and 23933 minutes with a mean of 4246.86±4050.903 minutes in the post-intervention group. There were no statistically significant differences between groups in the length of time receiving mechanical ventilation (p=0.203) (Table 8).

Table 8
Clinical Outcomes

Outcome	Total n	Pre-intervention n	Post -intervention n	pValue
Extubation	129	63	66	**0.051**
Pass	119	55	64	
Fail	10	8	2	
Ventilator Associated Pneumonia	129	63	66	0.143
Yes	35	22	13	
No	44	20	24	
Ventilation < 48 hours	50	21	29	
Length of Time on Mechanical Ventilation (minutes)	129	63	66	0.203
Mean		5162.76	4246.86	
Standard Deviation		4078.612	4050.903	

Table 9
Rate of Ventilator Associated Pneumonia

Formula	Pre-intervention	Post-intervention
# patients with VAP on ventilator X 1000 # mechanical ventilator days	22 X 1000 204	13 X 1000 166
= rate as incidence per 1000 ventilator days	=107.8 per 1000 ventilator days	=78.3 per 1000 ventilator days
#patients with VAP #patients at risk	22 42	13 37
=rate as a % of patients	=52.4%	=35.1%

Factors Affecting Clinical Outcomes

The relationships among rate of failed extubations, rate of ventilator associated pneumonia, and length of time on mechanical ventilation, and Acute Physiology and Chronic Health Evaluation (APACHE) II score, age, gender, reason for intubation, Riker Sedation Agitation Scale (SAS), head of bed elevation, placement of feeding tube, and subglottic secretion drainage using EVAC ™ tubes that incorporate a separate lumen ending into the subglottic area for drainage of secretions, were examined using a Chi-square test. The relationship between rate of ventilator associated pneumonia and length of time receiving mechanical ventilation was examined using an independent t-test.

A statistically significant relationship was observed between rate of ventilator associated pneumonia and reason for intubation ($p=0.015$). The other statistically significant relationships were observed between length of time on mechanical ventilation, and Acute Physiology and Chronic Health Evaluation (APACHE) II score ($p=0.043$) and reason for intubation ($p=0.005$). The length of time on mechanical ventilation was measured as either less than or greater than 72 hours. No statistically significant relationships were observed with rate of failed extubations. A statistically significant

relationship was observed between rate of ventilator associated pneumonia and length of time receiving mechanical ventilation. The mean length of time receiving mechanical ventilation for those patients who acquired ventilator associated pneumonia (n=35) was 8675.49±4302.09 minutes, or 144.5±71.7 hours; and the mean length of time receiving mechanical ventilation for those patients who did not acquire ventilator associated pneumonia was (n=44) 5210.84±2992.87 minutes, or 86.8±49.8 hours ($p<0.001$).

Practice Outcomes

The practice outcomes of this study were: the multidisciplinary staff's understanding of the mechanical ventilation weaning protocol; the multidisciplinary staff's perceptions of the safety climate; and the compliance rate of utilizing the mechanical ventilation weaning protocol. The multidisciplinary staff's understanding of the mechanical ventilation weaning protocol was assessed by the Protocol Directed Weaning Survey (Appendix E) and focus group sessions. The multidisciplinary staff's perceptions of the safety climate was assessed by the Safety Climate Survey (Appendix D) and focus group sessions. The compliance rate of utilizing the mechanical ventilation weaning protocol was assessed by continuous adherence to the GSICU Mechanical Ventilation Weaning Protocol.

Multidisciplinary Staff Demographics

The participants in the focus groups, protocol directed weaning survey, and safety climate survey, were clinical staff of various disciplines, the majority Registered Nurses (pre-intervention 67.9%; post-intervention 86.7%) and Respiratory Therapists (pre-intervention 16.1%; post-intervention 6.7%), who had a range of less than 1 year and greater than 20 years of experience in position, experience in speciality, and experience

in organization. The majority of the participants had a work status of permanent full time (pre-intervention 66.1%; post-intervention 60.0%). Only 17 of the clinical staff completed the safety climate survey both pre-intervention and post-intervention. The clinical staff participation and demographics are illustrated in Table 10 and 11, respectively.

Table 10
Clinical Staff Participation with PDSA Cycles

PDSA Cycle	n
Focus Groups	112
Completed Safety Climate Survey	112
Completed Protocol Directed Weaning Survey	112
Learning Sessions	101
Resurvey Sessions	31
Completed Safety Climate Survey	30
Completed Protocol Directed Weaning Survey	31

Table 11
Clinical Staff Demographics

Demographic Question	Pre-intervention n	%	Post-intervention n	%	pValue
Have you ever complete this survey before?	112		30		<0.001
Yes	0	0	17	56.7	
No	109	97.3	8	26.7	
Don't know	0	0	2	6.7	
Missing	3	2.7	3	10.0	
Job Position	112		30		
Attending/staff physician	3	2.7	0	0	0.401
Resident	2	1.8	0	0	
Pharmacist	0	0	0	0	
Staff Nurse	76	67.9	26	86.7	
Nurse Manager	1	0.9	1	3.3	
Respiratory Therapist	18	16.1	2	6.7	
Physical Therapist	2	1.8	0	0	
Nursing Attendant	3	2.7	0	0	
Other	0	0	0	0	
Missing	7	6.3	1	0	
Experience in position	112		30		
< 6 months	5	4.5	1	3.3	0.093
6 to 11 months	14	12.5	1	3.3	
1 to 2 years	12	10.7	9	30.0	
3 to 7 years	28	25.0	3	10.0	
8 to 12 years	14	12.5	3	10.0	
13 to 20 years	16	14.3	5	16.7	
21 years of over	18	16.1	5	16.7	
Missing	5	4.5	3	10.0	
Experience in speciality	112		30		
< 6 months	5	4.5	1	3.3	0.533
6 to 11 months	10	8.9	1	3.3	
1 to 2 years	13	11.6	8	26.7	
3 to 7 years	32	28.6	7	23.3	
8 to 12 years	13	11.6	3	10.0	
13 to 20 years	14	12.5	4	13.3	
21 years of over	18	16.1	4	13.3	
Missing	7	6.3	2	6.7	
Experience in organization	112		30		
< 6 months	7	6.3	0	0	0.192
6 to 11 months	7	6.3	1	3.3	
1 to 2 years	10	8.9	8	26.7	
3 to 7 years	30	26.8	6	20.0	
8 to 12 years	12	10.7	5	16.7	
13 to 20 years	20	17.9	5	16.7	
21 years of over	13	11.6	4	13.3	
Missing	13	11.6	1	3.3	
Age	112		30		
< 30	29	25.9	8	26.7	0.842
30-34	18	16.1	4	13.3	
35-39	16	14.3	3	10.0	
40-44	14	12.5	6	20.0	
45 or over	26	23.2	8	26.7	
Missing	9	8.0	1	3.3	
Work Status	112		30		
Permanent full time	74	66.1	18	60.0	0.767
Permanent part time	23	20.5	8	26.7	
Temporary full time	1	0.9	1	3.3	
Temporary part time	1	0.9	0	0	
Casual	6	5.4	2	6.7	
Missing	7	6.3	1	3.3	

Protocol Directed Weaning Understanding

The Protocol Directed Weaning Survey was a survey designed to test the staff's understanding of evidence based protocol directed weaning, and consisted of three questions with five possible points for each question for a total of 15 points (Appendix E). Clinical staff in both the pre-intervention and post-intervention groups were able to list five risks of prolonged mechanical ventilation (pre-intervention, 4.61±0.740; post-intervention, 4.61±0.803, p=0.970). Identification of five risks of reintubation improved following the learning sessions (pre-intervention, 4.06±1.180; post-intervention, 4.45±.780, p=0.031) as did the five criteria of "readiness to screen" which assist the clinician in determining whether a patient is ready to wean from mechanical ventilation with a mean and standard deviation of (pre-intervention, 1.15±.893; post-intervention, 3.68±1.620, p<0.001). Overall correct responses improved following the learning sessions (pre-intervention, 9.82±2.119; post-intervention 12.81±2.167, p<0.001) (Table 12).

Table 12
Protocol Directed Weaning Survey Results

Survey Question	Group	n	Mean	Std. Deviation	pValue
List five risks of prolonged mechanical ventilation.	pre-intervention	112	4.61	0.740	0.970
	post-intervention	31	4.61	0.803	
List five risks of reintubation.	pre-intervention	112	4.06	1.180	**0.031**
	post-intervention	31	4.45	0.768	
List five criteria of "readiness to screen" which assist the clinician in determining whether a patient is ready to wean from mechanical ventilation.	pre-intervention	112	1.15	0.893	**<0.001**
	post-intervention	31	3.68	1.620	
Total score	pre-intervention	112	9.82	2.119	**<0.001**
	post-intervention	31	12.81	2.167	

Safety Climate

Safety Climate refers to a culture of safety that encourages data collection and reporting (Piotrowski & Hinshaw, 2002), reducing blame, involving leadership (Wong, 2002), or focusing on systems (Krumberger, 2001). Theoretical components required in constructing a culture of safety are: commitment to safety is articulated at all levels of an organization; commitment to safety is articulated in providing necessary resources, incentives, and rewards; the primary priority is safety and this may mean production and efficiency may be secondary priorities; communication at and between all levels is frequent and candid; unsafe acts are rare despite high levels of production; errors and problems are transparent when they occur; organizational learning is a shared value; and behaviour at all levels focuses on problem solving to improve the system rather than on individual blame (Singer et al., 2003). The safety climate was assessed by the Safety Climate Survey (Appendix D). The questionnaire consisted of 19 questions plus demographic information, and uses a six point scale: not applicable, agree strongly, agree slightly, neutral, disagree slightly to disagree strongly.

The results of the safety climate survey are illustrated in Table 13. There were no statistically significant differences in response to the safety climate pre-intervention versus post-intervention. Consistently across both the pre-intervention and post-intervention groups, the majority of the clinical staff perceived the culture of the GSICU as easy to learn from the mistakes of others (pre-intervention, 61.1%; post-intervention, 66.6%); the senior leaders in the hospital listen and care about concerns (pre-intervention, 54.9%; post-intervention, 53.4%); the physician and nurse leaders in the GSICU listen and care about concerns (pre-intervention, 75.9%; post-intervention, 73.4%); their

suggestions about safety would be acted upon if they expressed them to management (pre-intervention, 49.5%; post-intervention, 66.7%); and management and leadership does not knowingly compromise safety concerns for productivity (pre-intervention, 59.1%; post-intervention, 60%). The majority of the clinical staff perceived that they were encouraged by their colleagues to report any safety concerns they may have (pre-intervention, 69.6%; post-intervention, 73.3%); they know the proper channels to direct questions regarding patient safety (pre-intervention, 79.6%; post-intervention, 80%); and they would feel safe being treated in the GSICU as a patient (pre-intervention, 70.1%; post-intervention, 66.7%). The majority of the clinical staff agreed that briefing personnel before the start of a shift is an important part of safety (pre-intervention, 81.8%; post-intervention, 89.6%); and that briefings are common in the GSICU (pre-intervention, 54.4%; post-intervention, 66.7%). The majority of the clinical staff were satisfied with the availability of clinical leadership from the physicians (pre-intervention, 83.3%; post-intervention, 96.7); nursing (pre-intervention, 83.7%; post-intervention, 90%); and pharmacy (pre-intervention, 78.3%; post-intervention, 83.3%). The majority of the clinical staff perceived that most adverse events occur as a result of multiple system failures, and are not attributable to one individual's actions (pre-intervention, 67.6%; post-intervention, 62.1%); that personnel in the GSICU take responsibility for patient safety (pre-intervention, 85.5%; post-intervention, 79.3%); and patient safety is constantly reinforced as the priority in the GSICU (pre-intervention, 64.3%; post-intervention, 50%). The majority of the clinical staff disagreed that personnel frequently disregard rules or guidelines that are established for the GSICU (pre-intervention, 54.9%; post-intervention, 60%).

The majority of the clinical staff in the pre-intervention group (50%) perceived that medical errors are handled appropriately in the GSICU, and the majority in the post-intervention group (44.8%) responded as neutral to medical errors being handled appropriately in the GSICU. The majority of the clinical staff were either neutral (pre-intervention, 38.4%; post-intervention, 34.5%) or agreed (pre-intervention, 46.4%; post-intervention, 55.1%) to the question that leadership is driving us to be a safety-centered institution. The majority of the clinical staff were neutral in responding to the question that the institution is doing more for patient safety now, than it did one year ago (pre-intervention, 50%; post-intervention, 62.1%). The majority of the clinical staff were either neutral (pre-intervention, 25.9%; post-intervention, 20%) or disagreed (pre-intervention, 45.3%; post-intervention, 53.3%) that they receive appropriate feedback about their performance.

Table 13
Safety Climate Survey Results

		disagree strongly %	disagree slightly %	neutral %	agree slightly %	agree strongly %	not applicable %	pValue
The culture of this clinical area makes it easy to learn from the mistakes of others.	preintervention n=108	3.7	12.0	22.0	37.0	24.1	0.9	0.153
	postintervention n=30	10.0	20.0	3.3	43.3	23.3	0	
Medical errors are handled appropriately in this clinical area.	preintervention n=108	4.6	11.1	32.4	30.6	19.4	1.9	0.715
	postintervention n=29	3.4	13.8	44.8	27.6	10.3	0	
The senior leaders in my hospital listen to me and care about my concerns.	preintervention n=111	6.3	18.9	18.0	31.5	23.4	1.8	0.970
	postintervention n=30	6.7	20.0	20.0	26.7	26.7	0	
The physician and nurse leaders in my areas listen to me and care about my concerns.	preintervention n=112	1.8	8.0	13.4	42.0	33.9	0.9	0.964
	postintervention n=30	3.3	6.7	16.7	36.7	36.7	0	
Leadership is driving us to be a safety-centered institution.	preintervention n=112	2.7	12.5	38.4	34.8	11.6	0	0.810
	postintervention n=29	0	10.3	34.5	37.9	17.2	0	
My suggestions about safety would be acted upon if I expressed them to management.	preintervention n=107	3.7	16.8	28.0	38.3	11.2	1.9	0.363
	postintervention n=30	3.3	6.7	23.3	60.0	6.7	0	
Management/leadership does not knowingly compromise safety concerns for productivity.	preintervention n=110	2.7	9.1	28.2	30.9	28.2	0.9	0.859
	postintervention n=30	6.7	6.7	26.7	36.7	23.3	0	
I am encouraged by my colleagues to report any safety concerns I may have.	preintervention n=112	0.9	10.7	18.8	37.5	32.1	0	0.948
	postintervention n=30	0	6.7	20.0	40.0	33.3	0	
I know the proper channels to direct questions regarding patient safety.	preintervention n=108	0	8.3	12.0	37.0	42.6	0	0.299
	postintervention n=30	0	0	20.0	40.0	40.0	0	
I receive appropriate feedback about my performance.	preintervention n=108	19.4	25.9	25.9	20.4	8.3	0	0.464
	postintervention n=30	33.3	20.0	20.0	23.3	3.3	0	
I would feel safe being treated here as a patient.	preintervention n=107	2.8	9.3	15.9	32.7	37.4	1.9	0.971
	postintervention n=30	3.3	10.0	20.0	30.0	36.7	0	
Briefing personnel before the start of a shift (i.e., to plan for possible contingencies) is an important part of safety.	preintervention n=110	0.9	2.7	13.6	30.9	50.9	0.9	0.670
	postintervention n=29	3.5	0	6.9	31.0	58.6	0	
Briefings are common here.	preintervention n=103	9.7	14.6	19.4	27.2	27.2	1.9	0.520
	postintervention n=30	6.7	3.3	23.3	36.7	30.0	0	
I am satisfied with the availability of clinical leadership . Physician	preintervention n=108	0.9	6.5	8.3	42.6	40.7	0.9	0.405
	postintervention n=30	0	3.3	0	60.0	36.7	0	
Nursing	preintervention n=110	0.9	6.4	8.2	45.5	38.2	0.9	0.952
	postintervention n=30	0	3.3	6.7	50.0	40.0	0	
Pharmacy	preintervention n=111	1.8	3.6	14.4	39.6	38.7	1.8	0.942
	postintervention n=30	0	3.3	13.3	43.3	40.0	0	
This institution is doing more for patient safety now, than it did one year ago.	preintervention n=112	3.6	9.8	50.0	22.3	6.3	8.0	0.890
	postintervention n=29	3.4	6.9	62.1	17.2	3.4	6.9	
I believe that most adverse events occur as a result of multiple system failures, and are not attributable to one individual's actions.	preintervention n=108	0.9	11.1	20.4	40.7	26.9	0	0.246
	postintervention n=29	6.9	13.8	17.2	27.6	34.5	0	
The personnel in this clinical area take responsibility for patient safety.	preintervention n=110	0.9	0.9	12.7	45.5	40.0	0	0.329
	postintervention n=29	0	6.9	13.8	48.3	31.0	0	
Personnel frequently disregard rules or guidelines that are established for this clinical area.	preintervention n=111	27.0	27.9	23.4	14.4	6.3	0.9	0.774
	postintervention n=30	40.0	20.0	23.3	10.0	6.7	0	
Patient safety is constantly reinforced as the priority in this clinical area.	preintervention n=112	4.5	11.6	19.6	38.4	25.9	0	0.280
	postintervention n=30	0	16.7	33.3	33.3	16.7	0	

Protocol Compliance

Protocol compliance was defined as adherence to and utilization of the GSICU Mechanical Ventilation Weaning Protocol for those patients who met eligibility criteria to be on the protocol and were enrolled in the study. Protocol compliance was determined by continuous adherence to the GSICU Mechanical Ventilation Weaning Protocol, and factors contributing to abatement of and adherence to the protocol were tabulated. The reasons for protocol abatement and adherence were usually recorded on the respiratory flow sheets, and interpreted daily by the researcher. When the reasons for abatement or adherence were not recorded on the flow sheet, the researcher recorded adherence as no with reason unknown.

There was a statistically significant difference in protocol compliance before and after the implementation program for a mechanical ventilation weaning protocol (pre-intervention, n=1; post-intervention, n=14, p=0.001). Table 14 summarizes the compliance with the GSICU Mechanical Ventilation Weaning Protocol. There was 1 case in the pre-intervention group where the protocol was followed; this patient was extubated > 24 hours after intubation. There were 14 cases in the post-intervention group where the protocol was followed; 9 patients (64.3%) were extubated < 24 hours after intubation. There were no cases of failed extubation with continuous adherence to the protocol.

The reasons for protocol abatement were: intraoperative myocardial infarction; planned surgery; decreased level of consciousness; sedative agent; paralytic agent; decreased tidal volume; increased respiratory rate; increased work of breathing;

desaturation; apnea; biting on ETT causing compression and unable to ventilate; and self-extubation.

Table 14
Protocol Compliance

	Total	Pre-intervention		Post-intervention		pValue
		n	%	n	%	
Continuous Adherence to Protocol	129	63		66		**0.001**
Yes	15	1	1.6	14	21.2	
No	114	62	98.4	52	78.8	

CHAPTER FIVE

Discussion

The purpose of this study was to assess the outcomes following an implementation program of a mechanical ventilation weaning protocol (Appendix B) for a heterogeneous adult critical care population in the GSICU at the University of Alberta Hospital. A prospective comparative design, before and after implementing The Model for Accelerating Improvement (Langley et al., 1996 as cited in Rainey et al., 1998), was used. The PDSA cycles of The Model for Accelerating Improvement were focus group sessions, surveys, learning sessions, and quantitative data collection. The clinical outcomes of this study were: rate of failed extubations; rate of ventilator associated pneumonia; and length of time on mechanical ventilation. The practice outcomes of this study were: multidisciplinary staff's understanding of the mechanical ventilation weaning protocol; multidisciplinary staff's perceptions of the safety climate; and compliance rate of utilizing the mechanical ventilation weaning protocol. Differences between pre-intervention and post-intervention groups on demographic and clinical characteristics, as well as clinical and practice outcomes were examined using an independent two-tailed t-test or Chi-square test as appropriate.

Clinical Outcomes

The sample consisted of 129 patients during a 5 month study period. Both the pre-intervention group (n=63) and post-intervention group (n=66) were similar with respect to demographic and clinical characteristics.

The rate of failed extubations was 12.7% in the pre-intervention group and 3.1% in the post-intervention group (p=0.051). Reported rates of reintubation range from 0.47

to 17% when comparing protocol or computer-directed weaning to physician directed weaning. In this study, the rate of failed extubations with protocol directed weaning led by a multidisciplinary team was less than reported in other studies comparing protocol directed weaning to physician or standard weaning practices (Burns et al., 2003; Chan et al., 2001; Dries et al., 2004; Ely et al., 1996; Kollef et al., 1997; Krishan et al., 2004; Saura et al., 1996). One of these studies reported a statistically significant reduction of failed extubations to 7.4% when protocol directed weaning was led by nurses and respiratory therapists ($p=0.013$) (Dries et al., 2004). All other studies did not reach statistical significance (Burns et al., 2003; Chan et al., 2001; Ely et al., 1996; Kollef et al., 1997; Krishan et al., 2004; Saura et al., 1996). Three studies comparing protocol or computer-directed weaning to physician directed weaning reported 'accidental' reintubation and reintubation rates less than this present study (Horst et al., 1998; Strickland & Hasson, 1993; Wood et al., 1995). In contrast, this present study observed a lower rate of reintubation for critically ill adults whose weaning was protocol directed compared to other studies (Burns et al., 2003; Chan et al., 2001; Dries et al., 2004; Ely et al., 1996; Horst et al., 1998; Kollef et al., 1997; Krishan et al., 2004; Saura et al., 1996; Strickland & Hasson, 1993; Wood et al., 1995). Reintubation carries an estimated eight times higher risk of noscomial pneumonia and six to twelve times increased mortality (Ely et al., 2001); and potentially induces harm due to associated airway trauma, gastric aspiration, acute lung injury, cardiovascular compromise, and hypoxic episodes (Esteban, Alía, Ibañex, et al., 1994). Thus, the findings of this clinical outcome may reduce the risk of nosocomial pneumonia, airway trauma, gastric aspiration, acute lung injury,

cardiovascular compromise, hypoxic episodes, and mortality in the General Systems Intensive Care Unit at the University of Alberta Hospital.

The rate of ventilator associated pneumonia was 52.4% in the pre-intervention group and 35.1% in the post-intervention group (p=0.143). Reported rates of ventilator associated pneumonia range from 1 to 20% when comparing protocol directed weaning to physician directed weaning (Dries et al., 2004; Kollef et al., 1998; Marelich et al., 2000). This study was similar to Marelich et al. (2000), in that there was a trend towards a decreased rate of ventilator associated pneumonia; yet different than Dries et al. (2004) who reported a statistically significant decreased rate of ventilator associated pneumonia following an implementation program of protocol directed weaning. Thus, in contrast with other randomized controlled and nonrandomized trials comparing protocol directed weaning to physician directed weaning, this study observed a higher rate of ventilator associated pneumonia with a clinically significant trend towards a decreased rate following an implementation program of a mechanical ventilation weaning protocol. This may be explained by the difference in definitions of VAP.

The mean length of time receiving mechanical ventilation in the pre-intervention group was and 5162.76$\pm$4078.61 minutes (86.0$\pm$67.9 hours) and 4246.86$\pm$4050.90 minutes (70.7$\pm$67.5 hours) in the post-intervention group (p=0.203). Reported length of time receiving mechanical ventilation when comparing protocol directed weaning to physician or computer-directed weaning ranges from 9.8 hours to 170.6 hours, and 2.9 days to 14.5$\pm$11.1 days, reported as 'duration for mechanical ventilation', 'average time receiving mechanical ventilation', 'mean duration of mechanical ventilation', 'median ventilation time', and 'median duration of mechanical ventilation (Burns et al., 1998;

Burns et al., 2003; Chan et al., 2001; Djunaedi et al., 1997; Dries et al., 2004; Duane et al., 2002; Ely et al., 1996; Foster et al., 1984; Grap et al., 2003; Horst et al., 1998; Kollef et al., 1997; Kollef et al., 1998; Krishan et al., 2004; Marelich et al., 2000; Saura et al., 1996; Strickland & Hasson, 1993; Wood et al., 1995). The length of time receiving mechanical ventilation was similar to other studies who reported a reduction in length of time on mechanical ventilation for critically ill adults whose weaning was protocol or computer-directed compared to those whose weaning was physician directed (Burns et al., 1998; Burns et al., 2003; Dries et al., 2004; Duane et al., 2002; Ely et al., 1996; Foster et al., 1984; Grap et al., 2003; Horst et al., 1998; Kollef et al., 1997; Kollef et al., 1998; Krishan et al., 2004; Marelich et al., 2000; Saura et al., 1996; Strickland & Hasson, 1993; Wood et al., 1995). This study was consistent with one randomized controlled trial and two nonrandomized trials in that the mean length of time receiving mechanical ventilation was reduced from long term or prolonged mechanical ventilation to mechanical ventilation less than three days (Dries et al., 2004; Kollef et al., 1997; Kollef et al., 1998). Thus, this clinical outcome may potentially reduce health care costs of the General Systems Intensive Care Unit, University of Alberta Hospital due to shorter intensive care unit stay and costs associated with mechanical ventilation which include risks of ventilator associated pneumonia and mortality, airway trauma, sedation needs (Cook et al., 1998; Marelich et al., 2000; Slutsky & Tremblay, 1998); and staff, patient, and family satisfaction (Burns, 1999).

Practice Outcomes

The practice outcomes were assessed with clinical staff of various disciplines, who had a range of less than 1 year and greater than 20 years of experience. One

hundred and twelve clinical staff completed the Protocol Directed Weaning Survey, and 18 of these clinical staff (16.1%) also completed this survey post-intervention. There was a statistically significant difference between the pre-intervention and post-intervention groups with an increase in protocol directed weaning understanding ($p<0.001$).

One-hundred and twelve clinical staff completed the safety climate survey pre-intervention, and 17 of these clinical staff (15.2%) also completed this survey post-intervention. The majority of the clinical staff perceived a positive safety climate both pre-intervention and post-intervention. The majority of the clinical staff were neutral in responding to the question that the institution is doing more for patient safety now, than it did one year ago, and the majority of the clinical staff were either neutral or disagreed that they receive appropriate feedback about their performance. There were no statistically significant differences between the pre-intervention and post-intervention groups with the Safety Climate of the GSICU at the University of Alberta Hospital.

This study observed an increased compliance rate following the weaning protocol when implemented with The Model for Accelerating Improvement. Protocol compliance pre-intervention was 1.6% versus 21.2% post-intervention ($p=0.001$). Reported rates of protocol compliance range from 10 to 100% when comparing protocol directed weaning to physician directed weaning (Burns et al., 2003; Duane et al., 2002; Krishnan et al., 2004). Determining protocol compliance to weaning from mechanical ventilation is in its infancy and little information about protocol compliance exists (Ely, Bennett, Bowton, et al., 1999). Randolph et al. (1998) evaluated compliance with computerized protocol directed weaning from mechanical ventilation and reported a compliance rate in following protocol of 66%. A program to monitor compliance was built into the

protocol, and user compliance in adhering to the protocol could be printed. From these results, The Model for Accelerating Improvement is recommended as a model for activating change (Randolph, 2003). Ely, Bennett, Bowton, et al. (1999) in a large-scale implementation of respiratory therapist driven protocol directed weaning from mechanical ventilation reported a compliance rate of >95% in obtaining and interpreting daily screening of weaning parameters. Compliance with the protocol was determined with morning assessments using daily screening parameters, followed with spontaneous breathing trials for those patients who had recovered from respiratory failure. Recovery from respiratory failure was determined with the passing of a daily screening test. Duane et al. (2002) measured compliance with protocol directed weaning and reported a compliance rate of 50 to 100% during the first year of its use with a decrease in compliance of 50% ten months following implementation. Protocol compliance was not explicitly defined. In a more recent study, Krishnan et al. (2004) reported a compliance rate with protocol directed weaning to be as high as 86.1%. Like other studies, protocol compliance was not explicitly defined. Thus, this current study is different from other trials in that protocol compliance was assessed before and after a protocol implementation program.

Thus, this study observed an increase in knowledge and utilization of the GSICU mechanical ventilation weaning protocol when implemented with The Model for Accelerating Improvement, and overall the clinical staff reported a positive safety climate with trends towards improving institutional patient safety and improving feedback about staff performance.

Limitations of the Study

The main limitation of this study is the small sample size of (pre-intervention, n=63; post-intervention, n=66). The implementation program and data collection was conducted over a five month period with less than a 50% response rate from the clinical staff. Perhaps more than five months should have been allocated to make significant changes to the clinical and practice outcomes, and to obtain a greater response rate from the clinical staff to consider the data valid.

There was also the possibility of clinician bias on the part of the nurses and respiratory therapists who were not blinded to the design of the research. The clinical staff may have favored and influenced the post-intervention group, and the possibility of this influence may explain the results. This bias was indicated by the clinical staff during a focus group session: "If the RTs and RNs have the ability with a weaning protocol then this means the go ahead to wean and extubate" (GSICU Respiratory Therapist, 2004).

Another limitation is the definition of study outcomes. Ventilator Associated Pneumonia was defined as the occurrence of progressive or new radiographic pulmonary infiltrates, cavitation, or pulmonary effusion from the onset of mechanical ventilation > 48 hours; one or more pathogens isolated from endotracheal aspirate, bronchoscopy cultures, or lung biopsy; and at least one of the following: fever $\geq 38.5^{\circ}$ C, leukocytosis WBC $\geq 10{,}000/mm^3$, and sputum change (new onset of purulent sputum, or change in character) (Marelich et al., 2000; Zack et al., 2002). There is an inconsistent approach to interpreting the chest radiographs by radiologists, an inconsistent approach in the method and indications in gathering of sputum samples, and inconsistent practices when initiating antibiotics. Furthermore, in the critically ill adult, some of the causes of a fever may be

blood transfusions, dehydration, extrapulmonary infection, or drug reaction; and some of the causes of leukocytosis may be a natural inflammatory reaction mediated by a surgical procedure, or an extrapulmonary infection. Additionally, when interpreting the rate of ventilator associated pneumonia the probability of aspiration with intubation or community acquired pneumonia was not considered. It has been suggested that ventilator associated pneumonia can be accurately diagnosed in the absence of gold standard criteria with quantitative culture and microscopic examination of lower respiratory tract secretions (Mayhall, 2001).

Protocol compliance was defined as the adherence to and utilization of the GSICU Mechanical Ventilation Weaning Protocol for those patients who meet eligibility criteria to be on the protocol. Protocol compliance was determined by continuous adherence to the GSICU Mechanical Ventilation Weaning Protocol, and factors contributing to abatement and adherence to the protocol were tabulated. Compliance to the protocol was not known unless narrative documentation on the respiratory board delineated whether the protocol was initiated or followed. The clinical staff indicated during a focus group session the need for determining adherence to protocol directed weaning: "We need a form to track weaning from shift to shift so we can see what they did on the last shift. We need documentation to see if the protocol is being followed, this should be on the RT board" (GSICU Respiratory Therapist, 2004).

Finally, regional critical care developments occurred during the study period that could have affected the results of this study. During the re-survey of the clinical staff's understanding of protocol directed weaning and safety climate, a local intensive care unit was on lock down for a Methicillin Resistant *Staphylococcus aureus* (MRSA) infectious

outbreak. The effects of this lock down meant changes in staffing patterns in the GSICU, an increased ratio of staff to patient in the GSICU, and regional bed utilization changes.

Implications of the Findings

The General Systems Intensive Care Unit at the University of Alberta Hospital implemented an evidence-based mechanical ventilation weaning protocol in December 2002, yet the extent of staff knowledge of this protocol was unknown. Pre-intervention data collection confirmed the compliance in utilizing the protocol was 1.6%. The Model for Accelerating Improvement, a process which guides health care teams in making procedural changes, was utilized to transfer an evidence-based mechanical ventilation weaning protocol to the practice setting. The prediction that by engaging the multidisciplinary team with a process of making procedural changes, staff and key stakeholders would be more likely to utilize the knowledge described in the literature was confirmed. This implementation process reduced the rate of failed extubations, improved the multidisciplinary staff's understanding of the mechanical ventilation weaning protocol, increased the compliance rate of utilizing the mechanical ventilation weaning protocol; and activated trends in reducing the rate of ventilator associated pneumonia, reducing the length of time receiving mechanical ventilation, and confirmed trends in constructing a culture of safety. Although, there is evidence suggesting that protocol directed weaning improves outcomes, there are no data to support endorsing any one specific protocol. The knowledge from the third step, 'Study' of these PDSA cycles builds sequentially for the start of a new PDSA cycle.

"A major challenge in implementing any protocol is the ability to sustain the protocol process." (Grap et al., 2003, p. 459). The clinical staff indicated during a focus

group session the need for sustainability: "The sedation protocol was great the first week out now we are back to doing the same stuff we did before…" (GSICU Registered Nurse, 2004). Limited information on sustainability of protocol directed weaning is available (Burns et al., 2003). Sustainability of protocol directed weaning in the GSICU will depend upon: endorsement of The Model for Accelerating Improvement at all levels of the organization, including leadership; rigorous continuing education about how to utilize the protocol; and re-evaluation of the protocol at a minimum annually as new evidence becomes available. Burns et al., (2003) suggest that sustainability of protocol directed weaning requires the presence of advanced practice nurses to guide the use and application of protocols. Endorsement of advanced practice nurses, or more specifically, utilizing advanced practice nurses to guide the use and application of evidence-based practice with The Model for Accelerating Improvement in the GSICU is strongly recommended. The clinical staff indicated during a focus group session the need for someone to spearhead evidence-based practice: "People need to know why we do something. You just can't come in and say do this weaning protocol. People need to know the science and research behind what we do and I think they will be a lot happier to go along with the protocol if there is good rationale and it makes sense rather than just having it show up one day on the chart" (GSICU Registered Nurse, 2004).

The fourth step of The Model for Accelerating Improvement is 'Act' which involves determining what modifications should be made, and preparing a plan for the next cycle. Currently, the GSICU Mechanical Ventilation Weaning Protocol is to be utilized continuously throughout the day and night, and can be initiated without a physician's order; however, night extubations are not a routine practice and extubations

require a physician's order. The clinical staff indicated in the focus groups a readiness to practice night extubations: "I think weaning should be around the clock practice. If someone wakes up in the middle of the night and they are gagging on the tube there should be no reason why we can't extubate in the middle of the night". It has been a traditional practice for intensive care units to extubate during the daytime, possibly increasing the risk of longer intensive care stays and associated costs, ventilator associated pneumonia, increased mortality, increased sedation needs, self-extubations, and decreased staff, patient, and family satisfaction. Endorsement of the GSICU Mechanical Ventilation Weaning Protocol, with PDSA cycles examining night extubations, and extubations with two clinician consensus and safe support systems in lieu of physician's orders are recommended.

The clinical staff indicated during the focus group sessions that protocols can improve the safety climate: "Protocol directed weaning will set a safety standard, trying to do something positive, trying to prevent injury and better the situation" (GSICU Respiratory Therapist, 2004). One participant said: "We need communication and trust one another…". Dissemination of information and knowledge utilization permeated every focus group session: "Group inservices are really good…Discuss the protocol at bedside rounds with all disciplines, especially the dieticians because if the patient is extubated it changes the way we feed them…Inservices about protocol directed weaning is essential…Education is needed with the RNs and RTs about the protocol so that the protocol will be successful". Future research utilizing PDSA cycles in the GSICU should address ways to construct a culture of safety, care for the caregiver, and dissemination of information and knowledge utilization.

The clinical staff indicated during the Safety Climate Survey the importance of the institution to do more for patient safety and to set standards of care: "Some people think they need a doctor's order to mobilize a patient, can we mobilize and wean without orders. We want standards of practice for nursing care, can RNs make judgements to mobilize or wean without an order or are RNs here just to follow orders, make it clear". Future PDSA cycles in the GSICU should address institutional safety for the patients, and standards of care. Some ideas are: the establishment of a medical emergency team to involve the GSICU bedside staff; sharing The Model for Accelerating Improvement with other units in the hospital to address areas for improvement; developing and testing a nursing kardex; and testing oral care products with mechanically ventilated patients.

The clinical staff indicated during the Safety Climate Survey and focus group sessions the importance of feedback about their performance: "I have been her for almost 3 years and I have yet to have a performance appraisal"; "Well, I've been her for 20 years and I have yet to have a performance evaluation". Future PDSA cycles in the GSICU should address staff performance feedback. Some ideas are: feedback at bedside rounds by educators, advanced practice nurses, and team leaders; allocating an area on the unit to post unit performance run-charts of PDSA cycles; exploring the possibility of peer evaluations; and focus groups with the staff to engage them in determining how they perceive performance feedback should be delivered. In addition, it is recommended the GSICU should re-survey the Safety Climate Survey following several PDSA cycles.

Even when research suggests that protocol directed weaning from mechanical ventilation improves outcomes for patients, the task of actively involving the multidisciplinary team to produce positive outcomes remains a challenge. "…research

evidence does not necessarily provide guidance on how to implement changes in individual intensive care units" (Chan et al., 2001 as cited in Wall, Robert, & Ely, 2001). Clinical staff participation with the focus groups and learning sessions were primarily Registered Nurses and Respiratory Therapists, and overall less than 50% of the staff participated with the PDSA cycles. The clinical staff indicated the need to involve the multidisciplinary team with new protocols: "Everybody has to be educated, not just one quarter of the staff for consistency"; "MDs have to be educated if we are going to implement a protocol, everybody has to be on board not just half of them, or one doing it their way or another doing it another way". Introducing the protocol to the Residents at the start of each GSICU rotation, for new employees during the orientation program, for those in clinical leadership roles, and for other disciplines is recommended.

Thus, the implications of this study suggest that clinicians have been meeting the challenges and assuming responsibility collectively, in narrowing the gap between current practice and evidence-based practice. However, ongoing multidisciplinary education and research by clinicians interested in improving outcomes supported by leadership utilizing The Model for Accelerating Improvement in the GSICU is essential. These PDSA cycles should build on knowledge sequentially with goals to address: decreasing the rate of ventilator associated pneumonia; increasing the compliance rate of following protocol directed weaning; increasing retention of skilled health care professionals; constructing a culture of safety at the University of Alberta Hospital; sustaining protocol directed weaning; care for the caregiver; and improving dissemination of information and knowledge. Some ideas for the start of these PDSA cycles are: endorsement of advanced practice nurses to guide the use and application of evidence-

based practice; practices of night extubations, and extubations with two clinician consensus and safe support systems in lieu of physician's orders; establishment of a medical emergency team to involve the GSICU bedside staff; sharing The Model for Accelerating Improvement with other units in the hospital to address areas for improvement; developing and testing a nursing kardex; testing oral care products with mechanically ventilated patients; providing feedback to clinical staff at the bedside; allocating an area on the unit to post unit performance run-charts of PDSA cycles; exploring the possibility of peer evaluations; provide focus groups with the staff to determine how they perceive performance feedback should be delivered; and introducing the protocol to the Residents at the start of each GSICU rotation, for new employees during the orientation program, for those in clinical leadership roles, and for other disciplines.

Conclusion

The implementation program for a mechanical ventilation weaning protocol using The Model for Accelerating Improvement (Langley et al., 1996 as cited in Rainey et al., 1998) reduced the rate of failed extubations, improved the multidisciplinary staff's understanding of the mechanical ventilation weaning protocol, increased the compliance rate of utilizing the mechanical ventilation weaning protocol; and activated trends in reducing the rate of ventilator associated pneumonia, reducing the length of time receiving mechanical ventilation, and confirmed trends in constructing a culture of safety. Thus, the discontinuation of mechanical ventilation guided by protocol directed weaning has been shown to balance against the possibility of premature extubation and unnecessary prolonged ventilatory support. All studies to date have compared protocol

or computerized directed weaning led by nurses and or respiratory therapists to physician or standard weaning practices. The uniqueness of this study is that it compared protocol directed weaning before and after an implementation program designed to engage a multidisciplinary team with a procedural change, utilizing The Model for Accelerating Improvement. Protocol directed weaning is recommended and is an effective and safe strategy in the management of mechanical ventilation with a heterogeneous adult critically ill population when implemented with The Model for Accelerating Improvement.

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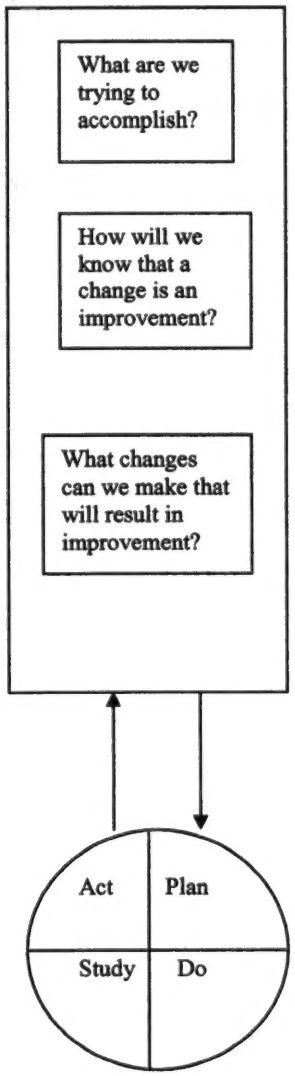
Appendix A

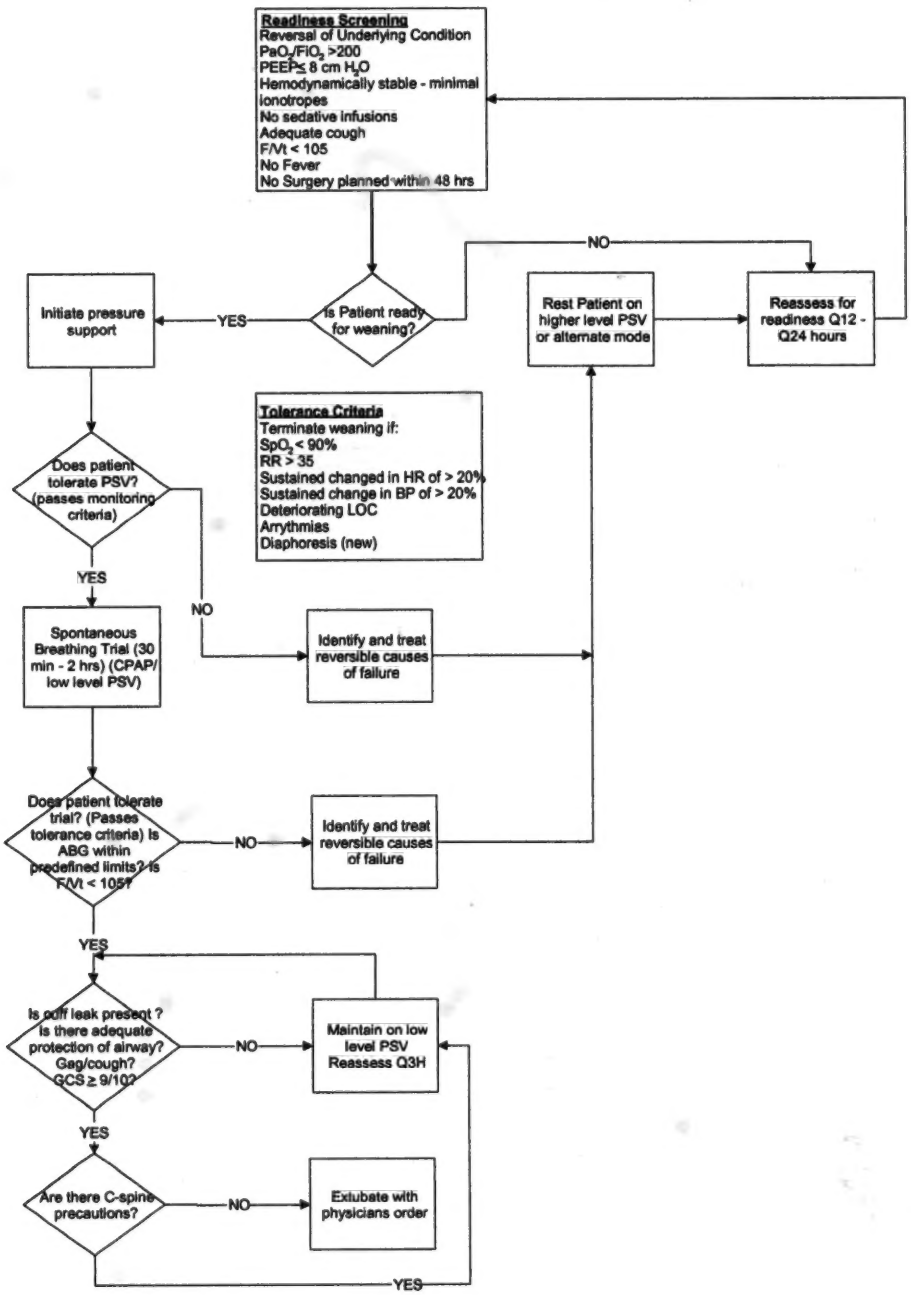
The Model for Accelerating Improvement


What are we trying to accomplish?
How will we know that a change is an improvement?
What changes can we make that will result in improvement?
Act
Plan
Study
Do

(Langley et al., 1996 as cited in Rainey et al., 1998)

Appendix B

GSICU Mechanical Ventilation Weaning Protocol


Readiness Screening
Reversal of Underlying Condition
PaO_2/FiO_2 >200
PEEP≤ 8 cm H_2O
Hemodynamically stable - minimal ionotropes
No sedative infusions
Adequate cough
F/Vt < 105
No Fever
No Surgery planned within 48 hrs
Is Patient ready for weaning?
NO
YES
Initiate pressure support
Rest Patient on higher level PSV or alternate mode
Reassess for readiness Q12 - Q24 hours
Tolerance Criteria
Terminate weaning if:
SpO_2 < 90%
RR > 35
Sustained changed in HR of > 20%
Sustained change in BP of > 20%
Deteriorating LOC
Arrythmias
Diaphoresis (new)
Does patient tolerate PSV? (passes monitoring criteria)
YES
NO
Spontaneous Breathing Trial (30 min - 2 hrs) (CPAP/ low level PSV)
Identify and treat reversible causes of failure
Does patient tolerate trial? (Passes tolerance criteria) Is ABG within predefined limits? Is F/Vt < 105?
NO
Identify and treat reversible causes of failure
YES
Is cuff leak present ? Is there adequate protection of airway? Gag/cough? GCS ≥ 9/10?
NO
Maintain on low level PSV Reassess Q3H
YES
Are there C-spine precautions?
NO
Extubate with physicians order
YES

Appendix C

Focus Group Outline

1. Explain the purpose of the focus group. *1 minute*
2. Administer Protocol Directed Weaning Survey and Safety Climate Survey. *8 minutes*
3. Guiding Questions: *21 minutes*

- Ask the participants to describe or share their understanding of protocol directed care.
- Ask the participants to describe or share their understanding of protocol directed weaning.
- Ask the participants to describe or share their experiences in utilizing protocol directed weaning.
- Ask the participants to describe or share their satisfaction in utilizing protocol directed weaning.
- Ask the participants to describe or share their dissatisfaction in utilizing protocol directed weaning.
- Ask the participants: How can Nurses, Respiratory Therapists, Physiotherapists, Dieticians, Pharmacists, Researches, Educators, and Physicians work together to achieve protocol directed weaning from mechanical ventilation.
- Ask the participants: What can be done as reminders to make the protocol easy to use, and difficult not to use.

Appendix D

Safety Climate Survey

Date:_____
Survey Number:_____

Please answer the following items with respect to your specific unit clinical Area. Choose your responses using the scale below:

	A	B	C	D	E	X
	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not Applicable
1. The culture of this clinical area makes it easy to learn from the mistakes of others.						
2. Medical errors are handled appropriately in this clinical area.						
3. The senior leaders in my hospital listen to me and care about my concerns.						
4. The physician and nurse leaders in my areas listen to me and care about my concerns.						
5. Leadership is driving us to be a safety-centered institution.						
6. My suggestions about safety would be acted upon if I expressed them to management.						
7. Management/leadership does not knowingly compromise safety concerns for productivity.						
8. I am encouraged by my colleagues to report any safety concerns I may have.						
9. I know the proper channels to direct questions regarding patient safety.						
10. I receive appropriate feedback about my performance.						
11. I would feel safe being treated here as a patient.						
12. Briefing personnel before the start of a shift (i.e., to plan for possible contingencies) is an important part of safety.						
13. Briefings are common here.						

14. I am satisfied with the availability of clinical leadership (please respond to all three): Physician						
Nursing						
Pharmacy						
15. This institution is doing more for patient safety now, than it did one year ago.						
16. I believe that most adverse events occur as a result of multiple system failures, and are not attributable to one individual's actions.						
17. The personnel in this clinical area take responsibility for patient safety.						
18. Personnel frequently disregard rules or guidelines that are established for this clinical area.						
19. Patient safety is constantly reinforced as the priority in this clinical area.						

Have you ever completed this survey before?

□Yes □No □Don't Know

Job Position (mark only one)

□Attending/Staff Physician

□Resident

□Pharmacist

□Staff Nurse

□Nurse Manager/Charge Nurse

□Respiratory Therapist

□Physical Therapist

□Dietician

□Nursing Attendant

□Other

Experience in Position:

□< 6 months □6 to 11 months □1 to 2 yrs □3 to 7 yrs
□8 to 12 yrs □13 to 20 yrs □21 yrs or over

Experience in Specialty:

□< 6 months □6 to 11 months □1 to 2 yrs □3 to 7 yrs
□8 to 12 yrs □13 to 20 yrs □21 yrs or over

Experience in Organization:

□< 6 months □6 to 11 months □1 to 2 yrs □3 to 7 yrs
□8 to 12 yrs □13 to 20 yrs □21 yrs or over

Age: □ <30 □ 30-34 □ 35 to 39 □ 40 to 44 □ 45 or over

Work Status: □ Permanent Full Time □ Permanent Part Time
□ Temporary Full Time □ Temporary Part Time
□ Casual □ Other_____

Sexton et al., 2003

Appendix E

Protocol Directed Weaning Survey:
Outcomes Following an Implementation Program of a Mechanical Ventilation Weaning Protocol for Critically Ill Adults

The purpose of this study is to measure the outcomes in implementing a mechanical ventilation weaning protocol with a heterogeneous adult critical care population at the University of Alberta Hospital, General Systems Intensive Care Unit. This survey is intended to provide information about the multidisciplinary team's understanding and awareness of the mechanical ventilation weaning protocol which was implemented in the GSICU in December 2002.

Your participation with this survey will remain anonymous. Your name will not be used in any of the reports or discussions about this study.

1. List five risks of prolonged mechanical ventilation.

   a.

   b.

   c.

   d.

   e.

Score: /5

2. List five risks of reintubation.

   a.

   b.

   c.

   d.

   e.

Score: /5

3. List five criteria of "readiness to screen" which assist the clinician in determining whether a patient is ready to wean from mechanical ventilation.

a.

b.

c.

d.

e.

Score: /5

Total Survey Score: /15

Please check one of the following with respect to your specific role within the multidisciplinary team:

- ☐ Nurse in charge
- ☐ Bedside Nurse
- ☐ Nurse Practitioner
- ☐ Clinical Nurse Educator
- ☐ Clinical Nurse Specialist
- ☐ Nursing Attendant
- ☐ Research Coordinator
- ☐ ICU Physician
- ☐ Resident
- ☐ Pharmacist
- ☐ Respiratory Therapist
- ☐ Dietician
- ☐ Physiotherapist
- ☐ Other_____

How many years of experience do you have in critical care?

- ☐ < 1
- ☐ 1-5
- ☐ 6-10
- ☐ 11-15
- ☐ 16-20
- ☐ >20

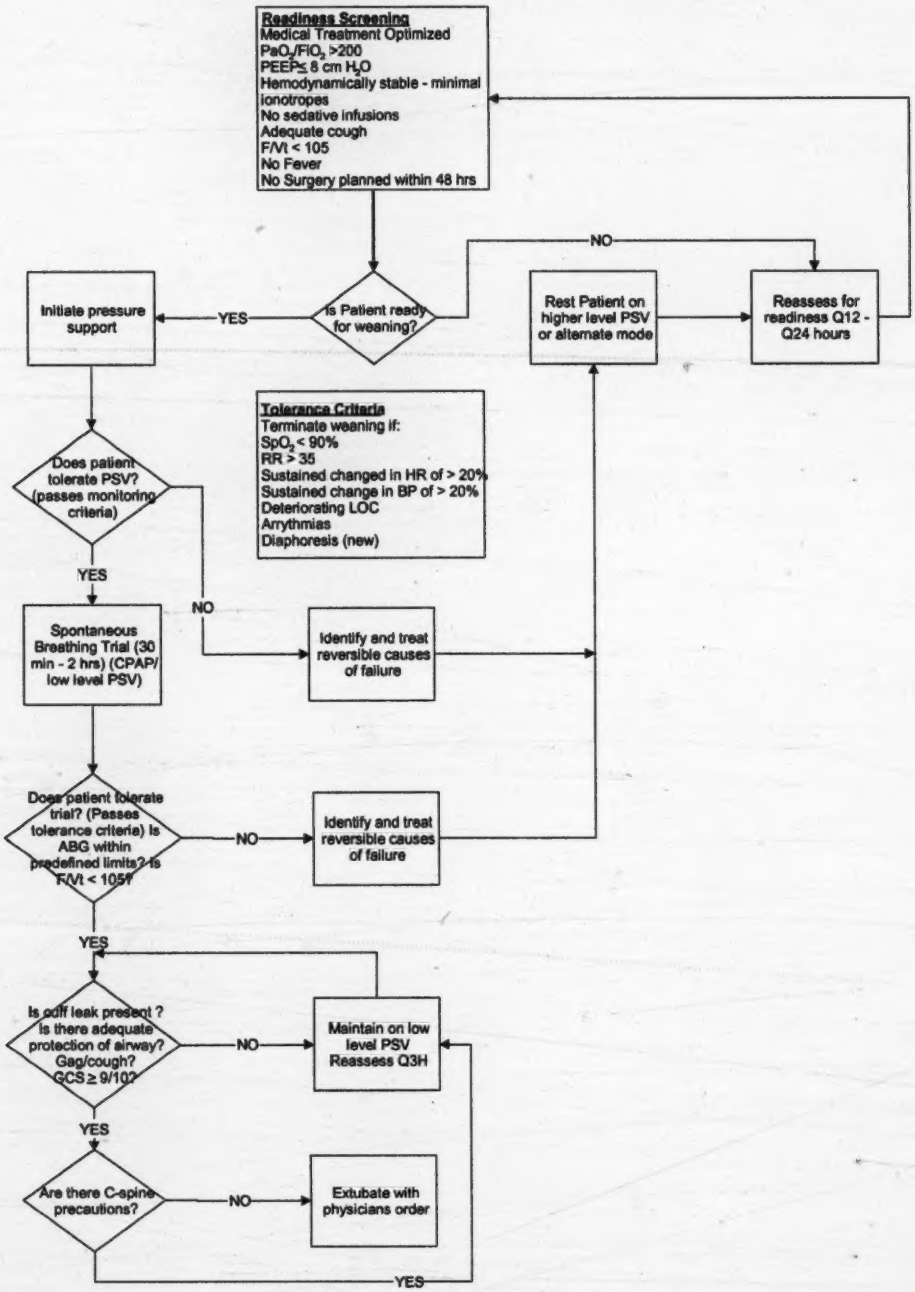
Work Status:

- ☐ Permanent Full Time
- ☐ Permanent Part Time
- ☐ Temporary Full Time
- ☐ Temporary Part Time
- ☐ Casual
- ☐ Other _____

Thank you for completing this survey.

Appendix F

GSICU Mechanical Ventilation Weaning Protocol


Readiness Screening
Medical Treatment Optimized
PaO2/FIO2 >200
PEEP≤ 8 cm H2O
Hemodynamically stable - minimal ionotropes
No sedative infusions
Adequate cough
F/Vt < 105
No Fever
No Surgery planned within 48 hrs
Is Patient ready for weaning?
YES
NO
Initiate pressure support
Rest Patient on higher level PSV or alternate mode
Reassess for readiness Q12 - Q24 hours
Tolerance Criteria
Terminate weaning if:
SpO2 < 90%
RR > 35
Sustained changed in HR of > 20%
Sustained change in BP of > 20%
Deteriorating LOC
Arrythmias
Diaphoresis (new)
Does patient tolerate PSV? (passes monitoring criteria)
YES
NO
Spontaneous Breathing Trial (30 min - 2 hrs) (CPAP/ low level PSV)
Identify and treat reversible causes of failure
Does patient tolerate trial? (Passes tolerance criteria) Is ABG within predefined limits? Is F/Vt < 105?
NO
Identify and treat reversible causes of failure
YES
Is cuff leak present ? Is there adequate protection of airway? Gag/cough? GCS ≥ 9/10?
NO
Maintain on low level PSV Reassess Q3H
YES
Are there C-spine precautions?
NO
Extubate with physicians order
YES

Appendix G

Minimum Data Set (MDS) Version 4 Illness Severity Score

Physiological Variables: lowest to highest in the first 24 hours

Variable	N/A	Lowest	Highest	Reference
Pulse				Beats/min
MAP				May use SBP/DBP
Core Temperature				Do not use postop T if not corrected
RR **Ventilated at any time during 1st 24 hrs? Y/N				Breaths/min
Oxygenation: Lowest P/F ratio from single ABG **Ventilated for this ABG? Y/N				mmHg
				mmHg
				% (not decimal or L)
pH				Not mixed venous
Hematocrit				% (not decimal)
WBC				X 10^9/L
Creatinine				mmol/L
Urine Output /24 hours				*If <24 hr, state # hrs
Urea				mmol/L
Sodium				mEq/L
Potassium				mEq/L
Albumin				g/L
Bilirubin				umol/L
Glucose				mmol/L

**Ventilated includes noninvasive and invasive positive pressure ventilation.
If only a single value for a variable: enter in Lowest box and dash the Highest box
If no ICU values for a variable: include ER values collected within 2 hours of ICU admission or if none collected in ER, check N/A.
*Asterisk to confirm extreme variance.

Martin, 2002

Minimum Data Set (MDS) V4 Illness Severity Score

Glasgow Coma Scale

Neurological Response	□ Eyes open spontaneously □ Eyes open but to verbal or painful stimuli □ Eyes do not open
Verbal Response *if intubated, judge likely response if no score assigned	□ Oriented and converses □ Confused but converses □ Inappropriate words/incomprehensible sounds □ No response
Motor Response	□ Obeys verbal commands □ Localizes pain □ Flexion withdrawal or decorticate rigidity □ Decerebrate rigidity □ No response
	If sedated/anesthetized (incl NMBA): use score from when effects have subsided. If during entire 1st 24 hrs, score as documented (i.e. 2/10 = 3/15)

Martin, 2002

Appendix H

Riker Sedation Agitation Scale (SAS)

Score	Description	Example
7	Dangerous agitation	Pulling ETT, trying to remove catheters, climbing over bed rail, striking at staff, thrashing side to side.
6	Very agitated	Does not calm despite frequent verbal reminding of limits, requires physical restraints, biting ETT.
5	Agitated	Anxious or mildly agitated, attempting to sit up, calms down to verbal instructions.
4	Calm and cooperative	Calm, awakens easily, follow commands.
3	Sedated	Difficult to arouse, awakens to verbal stimuli or gentle shaking but drifts off again, follow simple commands.
2	Very sedated	Arouses to physical stimuli but does not communicate or follow commands, may move spontaneously.
1	Unarousable	Minimal or no response to noxious stimuli, does not communicate or follow commands.

Riker, et al. 1999

Appendix I

Daily Data Collection Record

Patient Case Number	
Date	
Gender - complete with admission only	Female___ Male___
Age (circle) complete with admission only	18-30 31-40 41-50 51-60 61-70 71-80 81-90 >90
Relevant Past Medical/Surgical History (circle) complete with admission only	CHF COPD Asthma Exacerbation Pneumonia ARDS Renal Failure Liver Disease GI disease Cancer Overdose Neurological/Trauma Transplant Sepsis Other
Current Smoker – complete with admission only	Yes___ No___
APACHE II score (circle)	0-4 5-9 10-14 15-19 20-24 25-29 30-34 ≥35
Cause of Respiratory Failure Reason for Intubation (circle)	CHF COPD Asthma Exacerbation Pneumonia ARDS Renal Failure Liver Disease

	GI disease Cancer Overdose Neurological/Trauma Transplant Sepsis Other
Mechanical Ventilation Hours	*Recorded as # minutes*
Intubation Tube	ETT___ EVAC ™___ Trach___
Size of intubation tube (circle)	6 7 8
Ventilation Mode (circle)	AC PCV PS T-piece CPAP Other
PEEP (circle)	<5 5-10 11-15 >15
FiO2 (circle)	<35 35-40 41-50 51-60 61-70 71-80 81-90 91-100
Respiration Rate (circle)	< 10 10-14 15-19 20-24 25-29 30-35 >35
Sustained change in Heart Rate > 20%	Yes___ No___
Sustained change in Blood Pressure > 20%	Yes___ No___
Temp (circle)	36-38.4 >38.4
SaO_2 (circle)	<90 >90

Arterial Blood Gases (circle)	PH <7.35, 7.35-7.45, >7.45 PCO_2 <35, 35-45, >45 PO_2 <60, 60-80, 80-100, >100
Pa/FiO_2	<200___ >200___
RSBI	<105___ >105___
Minute ventilation (circle)	<10 1 0-14 15-19 >19
Sedative drip	Yes___ No___
Analgesic drip	Yes___ No___
Inotrope drip	Yes___ No___
Analgesic	Yes___ No___
Sedative	Yes___ No___
Paralytic Agents	Yes___ No___
Riker Sedation-Agitation Scale	*Recorded 0-7*
GCS (circle)	3 4-5 6-7 8-9 9-10 11-12 12-13 14-15
Cough/Gag (circle)	Absent___ Weak___ Moderate___ Strong___
Arrhythmias	Yes___ No___
Diaphoresis	Yes___ No___
Abdominal Paradox	Yes___ No___
Hemoglobin (circle)	<70 70-80 81-90 >90
Cuff leak	Yes___ No___
Surgery planned within 48 hours	Yes___ No___
C-spine precautions	Yes___ No___
WBC	*Recorded as narrative*
Tracheal tube pathogen isolated from aspirate or bronchoscope cultures	Yes___ Pathogen_____ No___
Sputum Change	Yes___ *Description as narrative* No___
Chest xray	*Description as narrative*
Ventilator Associated Pneumonia	Yes___ No___
Head of Bed Elevation	<30___ >30___
Post pyloric feeding	Yes___ No___

Protocol initiated	Yes___ No___ If No, reason why (*Recorded as narrative*)
Protocol being followed	Yes___ No___ If No, reason why (*Recorded as narrative*)
Reintubation within 48 hours of extubation	Yes___ No___

Appendix J

Multidisciplinary Team Member Information Letter:
Outcomes Following an Implementation Program of a
Mechanical Ventilation Weaning Protocol for Critically Ill Adults

Dear Team Member:

The purpose of this study is to assess the outcomes in implementing a mechanical ventilation weaning protocol with a heterogeneous critically ill adult population at the University of Alberta Hospital, General Systems Intensive Care Unit.

There is evidence suggesting that protocol directed weaning improves patient outcomes, and reduces the duration of mechanical ventilation. Minimal research has been dedicated to the process of implementing a mechanical ventilation weaning protocol with a multidisciplinary team.

We are interested in assessing the change in practice following an implementation program of a mechanical ventilation weaning protocol for critically ill adults.

If you decide to participate in this study you will be expected to attend a focus group session, a learning session, and complete a Safety Climate Survey and Protocol Directed Weaning Survey. The surveys will be completed during the focus group and learning sessions. Your responses will be anonymous. Only the researcher will have access to individual responses.

The purpose of the these sessions is to gain an understanding of the multidisciplinary staff's perceptions about the current procedure of protocol directed weaning, improve the multidisciplinary staff's understanding and utilization of the mechanical ventilation weaning protocol, and assess the multidisciplinary staff's perceptions of the safety climate following an implementation program for a mechanical ventilation weaning protocol.

The focus group will last approximately 30 minutes and will be tape recorded. All personal identification will be removed from the tape recording before transcription. Approximately one to two months after the focus group, learning sessions will be offered. The learning session will last approximately 30 minutes. You may attend the focus group or learning session during your shift, and they will be offered during the day and night shifts.

If you decide not to participate in this study, your decision will not affect your employment position. Your participation, feedback, comments, suggestions, concerns are welcomed and encouraged. You may contact me via pager at 445-3489, or my Faculty Supervisor, Dr. Louise Jensen at 492-6795.

Sincerely,

Suzanne E. McLean, MN Candidate

Appendix K

Learning Session Outline

1. Explain the purpose of the learning session. *1 minute*

2. Using a power point presentation the following topics will be discussed.

   - Indications for mechanical ventilation *1 minute*
   - Risks of prolonged mechanical ventilation *1 minute*
   - Risks of reintubation *1 minute*
   - Definition of Ventilator Associated Pneumonia and strategies to prevent *1 minute*
   - Discuss predictors of successful weaning *1 minute*
   - Discuss process of weaning *1 minute*
   - Overview of randomized controlled trials examining protocol directed weaning *4 minutes*
   - Discuss Model for Accelerating Improvement: *4 minutes*
     i. What are we trying to accomplish?
        1. increase rate of successful extubations
        2. decrease rate of ventilator associated pneumonia
        3. decrease time spent receiving mechanical ventilation
        4. increase multidisciplinary staff's understanding of the mechanical ventilation weaning protocol
        5. improve the multidisciplinary staff's perceptions of the safety climate

6. increase compliance rate of utilizing mechanical ventilation weaning protocol

ii. How will we know a change is an improvement?

1. The participants will be asked for their input with this

iii. What changes can we make that will result in an improvement?

1. The participants will be asked for their input with this

- Walk through the GSICU Mechanical Ventilation Weaning Protocol *5 minutes*

3. Administer Protocol Directed Weaning Survey and Safety Climate Survey. *8 minutes*

Appendix L

PATIENT AND FAMILY INFORMATION SHEET

Research Title: Outcomes Following an Implementation Program of a Mechanical Ventilation Weaning Protocol for Critically Ill Patients

Investigator: Suzanne E. McLean, RN, MN Candidate
(780) 988-1242

Supervisor: Louise Jensen, RN, PhD
(780) 492-6795

Introduction and Purpose:
If you are consenting on behalf of a third party, "you" should be read as "your relative". You or your family member are being asked to participate in a study to assess the outcomes of a teaching program to enhance the use of a mechanical ventilation weaning protocol (a process to wean the amount of support the breathing machine provides). When patients have trouble breathing, a tube is usually placed in their mouth and the mechanical ventilator (breathing machine) supports the breathing. Most of the patients admitted to the intensive care unit (ICU) require this support in breathing. Currently there are different methods to discontinue mechanical ventilation and this is referred to as weaning from mechanical ventilation. It is believed that one standard method to wean you from the ventilator (weaning protocol) will reduce the risk of failing extubation (having to be put back on the breathing machine), reduce the risk of acquiring pneumonia (infection), and also reduce the time spent on the ventilator. This weaning protocol was started in December 2002. The researcher will be meeting with your health care providers to teach and discuss the weaning protocol. It is thought that by teaching the ICU team about the weaning protocol, they will be more likely to use this method.

Requirements and Procedures:
Your consent to participate in this study will only involve the researcher obtaining information from your hospital chart. The information obtained from your chart will include past and current medical and surgical history, and values about how your body responds to the breathing machine and the amount of support the breathing machine provides. This information will be collected from intubation (the day the breathing tube is inserted) to 48 hours post-extubation (48 hours after the breathing tube is removed).

Potential Benefits:
There are no medical benefits that can be guaranteed to you for participation in this study. You may benefit from the knowledge that your participation in this study will guide the use of the weaning protocol. There is a chance that you may spend less time receiving mechanical ventilation (less time on the breathing machine), reduce the chance of acquiring pneumonia (infection), and reduce the chance of having to be reintubated (having the breathing tube put back in).

Risks:
There will be no adverse effects associated with participation in this study. In no situation will the study interfere with delivery of your care or the support you require from the breathing machine. If you were to show any signs of not tolerating the decreases in mechanical ventilation support, you would be given as much ventilation support as required.

Confidentiality:
All information recorded about you will be kept confidential. Your name will not be used in any of the reports or discussions about this study. You will be assigned a case number, and you will be identified only by this case number on all chart information collected related to the study. A list of the case study numbers corresponding to your name will be maintained in an administrative office separate from the information collected. By signing the consent form, you give permission to the study staff to access personally identifiable health information that is under the custody of other health care professionals as deemed necessary for the conduct of this research.

Voluntary Participation and Consent:
The decision to participate in this study is voluntary. You may refuse or withdraw from this study at any time, and your decision will not affect the delivery of care you receive.

Contact Persons:
You may contact the principal researcher, Suzanne McLean at (780) 988-1242 or Dr. Louise Jensen at (780) 492-6795, should you have any questions and/or concerns about this study.

If you have any concerns and/or questions concerning your rights as a patient in an investigational study, you may contact the Patient Relations Office at (780) 407-1040.

Appendix M

CONSENT FORM

Part 1 (to be completed by the Principal Investigator):

Title of Project:	Outcomes Following an Implementation Program of a Mechanical Ventilation Weaning Protocol for Critically Ill Adults		
Principal Investigator:	Suzanne E. McLean	Nursing	(780) 988-1242
Co-Investigators:	Dr. Louise A. Jensen	Nursing	(780) 492-6795
	Dr. Carolyn J. M. Ross	Nursing	(780) 492-4894
	Dr. Neil M. Skjodt	Pulmonary Medicine	(780) 407-6217
	Dr. Noel R.T. Gibney	Critical Care Medicine	(780) 407-1360

Part 2 (to be completed by the research subject):	**Yes**	**No**
Do you understand that you have been asked to be in a research study?		
Have you read and received a copy of the attached Information Sheet?		
Do you understand the benefits and risks involved in taking part in this research study?		
Have you had an opportunity to ask questions and discuss this study?		
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?		
Has the issue of confidentiality been explained to you?		
Do you understand who will have access to your records, including personally identifiable health information?		
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name_____		
Who explained this study to you?_____		

I agree to take part in this study: YES NO

Signature of Patient/Family Member_____

Printed Name of Patient/Family Member_____

Date:_____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or
Designee_____Date_____